

COVID-19 Vaccination Plan

DISTRICT OF COLUMBIA

NOVEMBER 27, 2020

DC HEALTH
GOVERNMENT OF THE DISTRICT OF COLUMBIA

WE ARE GOVERNMENT OF THE
DISTRICT OF COLUMBIA
DC MURIEL BOWSER, MAYOR

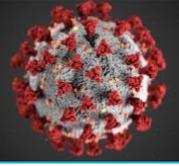
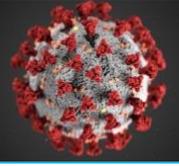


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District of Columbia COVID-19 Vaccination Plan: Executive Summary

Introduction

In response to the Coronavirus Disease 2019 (COVID-19) pandemic, the District of Columbia (District or DC) officially activated a multi-agency response, coordination, and recovery effort with an integrated Emergency Operations Center (EOC) at DC Health's Health Emergency Coordination Center on March 11, 2020. The District of Columbia Department of Health (DC Health) has led the public health response to this pandemic through implementing equitable programs and policies to promote health and protect the safety of residents, visitors, and those doing business in the nation's capital. The Director of DC Health serves as the chief public health advisor and strategist to the EOC and District Mayor Muriel Bowser. The COVID-19 Vaccine Group is organizationally within the EOC and staffed by subject matter experts within DC Health. This group's purpose is to plan and execute a safe and equitable distribution and administration of an eventual COVID-19 Vaccine to the District workforce and residents.

The District's geographic location between Maryland and Virginia lends itself to significant population movement between all three jurisdictions. These individuals who reside outside of the District are part of the necessary workforce and critical infrastructure that keeps the District functioning. DC's COVID-19 Vaccination Plan has included population vaccination estimates of those who reside in another state but work in the District as healthcare workers and critical infrastructure personnel. Therefore, the District's initial and subsequent federal COVID-19 vaccine allotment must be based on the District's workforce population and not only the District residency population.

The District's COVID-19 Vaccination Plan outlines an infrastructure to support a coordinated response to vaccine distribution and administration for healthcare workers, critical infrastructure workers, specific vulnerable populations, those with a higher risk of severe morbidity and mortality due to COVID-19, as well as all District residents. This draft plan is strengthened through continuous engagement with external partners such as the District's Health and Medical Coalition, ImmunizeDC Community Organization, and the DC Health's Scientific Advisory Committee.

COVID-19 Vaccination Planning Sections:

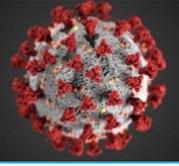
Section 3: Phased Approach to COVID-19 Vaccination

The District is considering the *National Academies of Science, Engineering, and Medicine Committee on Equitable Allocation of Vaccine for the Novel Coronavirus's* Framework for equitable allocation of COVID-19 vaccine to inform an ethical phased approach.

DC will implement a plan based on the three phased approach outlined by the CDC; however, the **driver will be the number of individuals within settings and not the number of residents**. This approach is informed from lessons learned the H1N1 Influenza pandemic and our review of standards of practice for vaccine allocation during pandemics. Our approach is based on current evidence, while recognizing the inherent uncertainties and the need for flexibility as new evidence emerges.

Section 4: Critical Populations

The District will count those who reside in another state but work in District healthcare facilities or as District critical infrastructure employees as part of those critical populations who will be allocated the



initial doses of the COVID-19 vaccination in the District. DC will communicate with agencies whose employees fall outside of allocation by key federal agencies (VA, DOD, DHS, BOP, IHS). However, the District of Columbia maintains that these federal agencies should be directly supported by a federal vaccine allotment dedicated specifically for federally agencies not engaged directly in the COVID-19 response or their state of residence's allotment based on their individual health risk as opposed to being supported by the initial local doses provided to the District. The estimate of Critical Workforce and Populations for Phase 1 of COVID-19 Vaccine Distribution was created using available information from DC government agencies, local community partners, CDC's Behavioral Risk Factor Surveillance System (BRFSS) for the District, and DC's Health and Medical Coalition Healthcare Workforce Survey.

Section 5: COVID-19 Vaccination Provider Recruitment and Enrollment

DC Health is transitioning to a new Immunization Information System (IIS) through its vendor STC Health. Provider Enrollment planning is a hybrid of an existing enrollment process and utilization of STC's IIS platform, STC|ONE. Provider recruitment is focused on Tier 1 groups that are able to receive, store, handle, and administer vaccines. STC|ONE will support rapid implementation and a single system transition.

Enrollment will occur via QuickBase application, separate from the IIS. Each facility has been sent a communication which includes a link via QuickBase to enroll providers. There will be three types of enrollments: *New User* for Clinical Decision or view access, *VFC User*, or *HL7* onboarding (may/may not order vaccine, be a VFC Provider, but reports electronically and has at least view access). Registration will be imported into STC|ONE to maintain a single source of information for all providers.

Section 8: COVID-19 Vaccine Storage and Handling

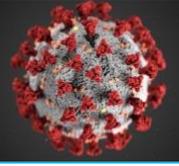
DC Health will utilize existing CDC guidance, recommendations, and modules on vaccine storage and handling, with modifications made based on requirements for final, available vaccines. All staff will be properly trained in vaccine storage and handling.

Section 10: COVID-19 Vaccination Second-Dose Reminders

A feature of the new IIS is *MyIR*, which includes a mobile tool that pushes out notifications (including second dose reminders) and is tied to geocoded scheduling information. Providers will be strongly encouraged to utilize their reminder/recall systems for both phases of vaccine distribution.

Section 12: COVID-19 Vaccination Program Communication

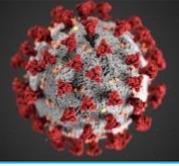
The District will use risk communication principles along with the CDC's recently developed *Vaccinate with Confidence* framework, to develop messaging and guide overall COVID-19 vaccination communication strategies and tactics. The *Scientific Advisory Committee for the Development and Implementation of a Safe, Effective, and Equitable COVID-19 Vaccine Distribution Program in the District of Columbia* will advise the Director of DC Health on effective strategies to communicate public health information regarding safety and effectiveness of the vaccine in order to promote vaccine confidence and uptake. The Scientific Advisory Committee will counsel on messaging and outreach strategies to counter misinformation regarding an eventual COVID-19 vaccine.



Section 14: COVID-19 Vaccine Safety Monitoring

Reporting of vaccine adverse events including vaccine administration errors will be included as part of the Cooperative Vaccine Agreement during enrollment, and monthly reminders to Providers. Information related to VAERS will be included in provider and staff training. Reporting of adverse events via online or writable PDF form (<https://vaers.hhs.gov/>) will be recommended. Additionally, adverse events should be submitted to the DC Reporting and Surveillance Center (DCRC) online reporting system located at <https://dchealth.dc.gov/service/infectious-diseases>.

DRAFT



Section 1: COVID-19 Vaccination Preparedness Planning

- A.** *Describe your early COVID-19 vaccination program planning activities, including lessons learned and improvements made from the 2009 H1N1 vaccination campaign, seasonal influenza campaigns, and other responses to identify gaps in preparedness.*

Starting in May of 2020, the District of Columbia Department of Health (DC Health) initiated preparation and planning for COVID-19 vaccination efforts in the District of Columbia (District or DC). At that time, in an effort to coordinate DC Health's approach to providing a COVID-19 vaccine to District residents, DC Health formed a preliminary planning team consisting of staff from the District of Columbia Immunization Program and DC Health Emergency Preparedness and Response Administration, to discuss vaccination strategy and planning. The initial goal of this small planning team was to maintain situational awareness and review relevant planning documents as they pertain to COVID-19 vaccination documents reviewed during the early stages of the planning process. This included:

- After Action Review from 2009 H1N1,
- Concept of Operations from 2009 H1N1,
- Points of Dispensing (POD) Site Plans from 2009 H1N1, and
- DC Health plans and prior exercises addressing Pandemic Influenza and Medical Countermeasures.

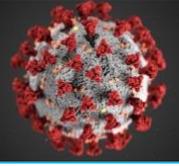
A review of documentation that followed the events of 2009 H1N1 focused on the primary areas for improvement detailed in the After Action Review. Key items identified for improvement that have been incorporated into planning for COVID-19 vaccination campaigns included overarching, programmatic recommendations for DC Health's Immunization program as well as tactical-level suggestions for the functionality of POD sites. Notably, DC Health has utilized these lessons learned to inform planning, such as procuring a new Immunization Information System (IIS) that will help to ease the process of scheduling mass vaccination events, vaccine ordering, and capturing vaccines administered.

Other documentation and relevant exercises that were reviewed include DC Health's Open Points of Dispensing (POD) plan as well as the National Capitol Region's Medical Countermeasure, POD Full-Scale Exercise that was conducted in July 2019.

The initial planning team focused efforts on developing a draft concept of operations including information on preliminary planning assumptions, drafting lists of materials for inclusion in POD kits, and identifying key community partnerships to leverage.

The continuation of DC Health's vaccination planning has included building a larger planning team to focus efforts on the identified priority areas of:

- Distribution and administration,



- Communication strategy,
- Vaccine logistics,
- Public dispensing,
- Vaccine technical assistance, and
- Epidemiology of SARS-CoV-2.

Utilizing the aforementioned priority areas, sections of the planning team were formed and expanded utilizing agency staff with subject matter expertise across and broad cross section of programs within DC Health.

- B.** *Include the number/dates of and qualitative information on planned workshops or tabletop, functional, or full-scale exercises that will be held prior to COVID-19 vaccine availability. Explain how continuous quality improvement occurs/will occur during the exercises and implementation of the COVID-19 Vaccination Program.*

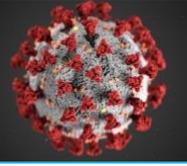
Starting in May 2020, the District started conducting discussion-based exercises as a part of the COVID-19 vaccination planning process. Lessons learned from the H1N1 response, COVID-19 Testing Operations, as well as the Regional Medical Countermeasures (MCM) Exercise have given the District knowledge of areas of improvement upon which to build and work through to ensure that the COVID vaccine campaign is successful. Some of the discussion-based exercises that the District has already conducted include:

- District Vaccine Operations: 9/22/2020, weekly ongoing discussions
- POD Logistics: 8/18/2020, monthly ongoing discussions
- Vaccine Data Management: 8/27/2020, monthly ongoing
- Vaccine Prioritization: 9/21/2020, weekly ongoing discussions

Listed below are the trainings/exercises that will take place in the form of a workshop, tabletop exercise, and/or drill. This list is to be completed by February 2021 in preparation for phase 2 vaccine distribution and POD site set-up. Specific dates are to be determined.

- Vaccine transport and security/Cold Chain Management
- POD Kit transport and security
- Vaccine data management
- Pre-registration/registration and screening
- Vaccine administration and distribution & anaphylaxis management
- POD supply
- POD resupply

DC Health will use quality improvement strategies such as Root-Cause Analysis, plan-do-study-act (PDSA) cycles, Gantt charts, and Fishbone diagramming leveraging the Lean Six Sigma infrastructure that is embedded within the city's public health agency. This will allow the District



to make improvements throughout the development and implementation of the COVID-19 vaccination program. These efforts will ensure the safety of every resident who receives the COVID-19 vaccine.

Section 2: COVID-19 Organizational Structure and Partner Involvement

A. Describe your organizational structure.

The District of Columbia officially activated a multi-agency response, coordination, and recovery effort with an integrated Emergency Operations Center (EOC) at DC Health's Health Emergency Coordination Center on March 11, 2020 in response to the Coronavirus Disease 2019 (COVID-19) pandemic. The EOC reports directly to District of Columbia Mayor Muriel Bowser. The DC Health Director, Dr. LaQuandra S. Nesbitt, serves within the Executive Policy Group of the EOC.

Additionally, since March 2020, the District's Health and Medical Response efforts have been coordinated under the Operations Section, Health and Medical Branch. A Vaccination Group was formed under the Health and Medical Branch in August 2020, to begin coordination of key internal and external stakeholders in the District. This group includes representatives from the immunization program, public health preparedness and response program, healthcare preparedness program, epidemiology surveillance program, health regulation and licensing experts, and communication and community relations. This group was tasked to develop plans and coordinate activities for the eventual COVID-19 vaccine. Figures 1, 2, and 3 outline this organizational structure.

DISTRICT OF COLUMBIA COVID-19 VACCINATION PLAN

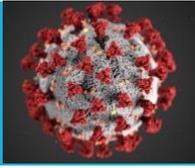


Figure 1.

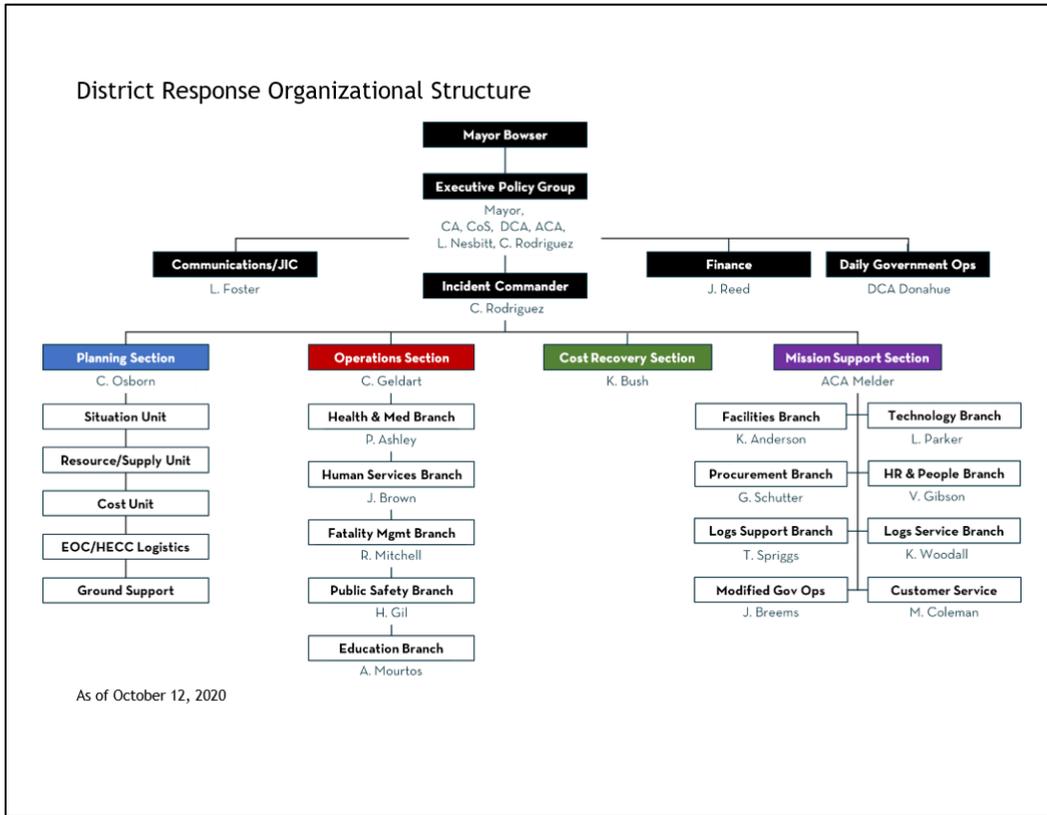
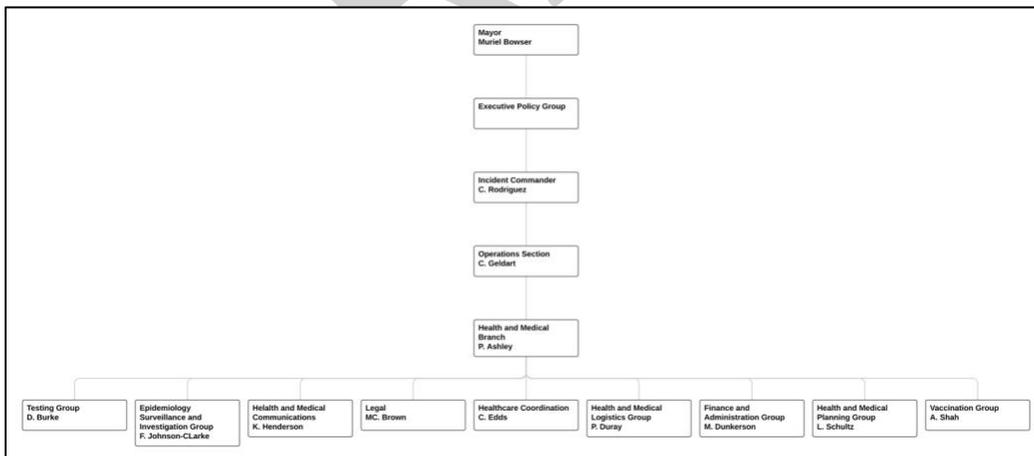


Figure 2.



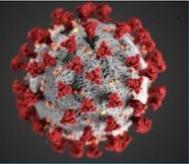
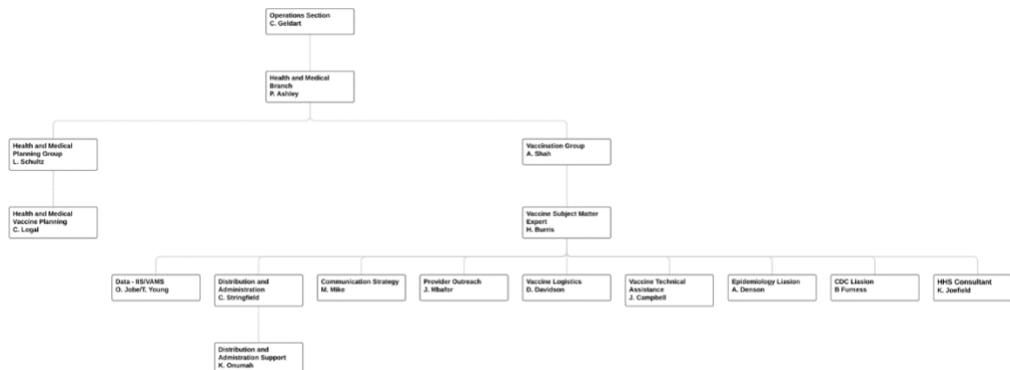


Figure 3.



In addition to the EOC structure, the D.C. Department of Health (DC Health), with partnering agencies (local and federal), is the lead agency responding to the COVID-19 pandemic in the District of Columbia. DC Health is led by Dr. LaQuandra S. Nesbitt, and has an Executive Structure of Senior Deputy Directors who oversee five separate administrations (See Figure 4.):

- **Center for Policy, Planning, and Evaluation (CPPE)** – assesses health issues, risks and outcomes through data collection, surveillance, analysis, research and evaluation; and perform state health planning functions.
- **Community Health Administration (CHA)** – promotes healthy behaviors and healthy environments to improve health outcomes and reduce disparities in the leading causes of disease and death in the District; and helps improve access to preventative services and care for all residents.
- **Health Emergency Preparedness and Response Administration (HEPRA)** – ensures the delivery of the highest quality emergency medical and trauma care services through the provision of regulatory oversight of all emergency medical services provided in the District.
- **Health Regulatory and Licensing Administration (HRLA)** – protects the health of the residents of the District of Columbia and those that do business by fostering excellence in health professional practice and building quality and safety in health-systems and facilities through an effective regulatory framework.
- **HIV/AIDS, Hepatitis, STD, and TB Administration (HAHSTA)** – prevents HIV/AIDS, STDs, Tuberculosis and Hepatitis, reduce transmission of the diseases and provide care and treatment to persons with the diseases.

Throughout this public health emergency, public health professionals across DC Health have been redeployed to focus on specific aspects of the District’s COVID-19 pandemic response.

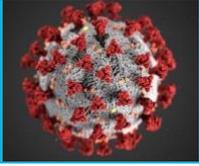
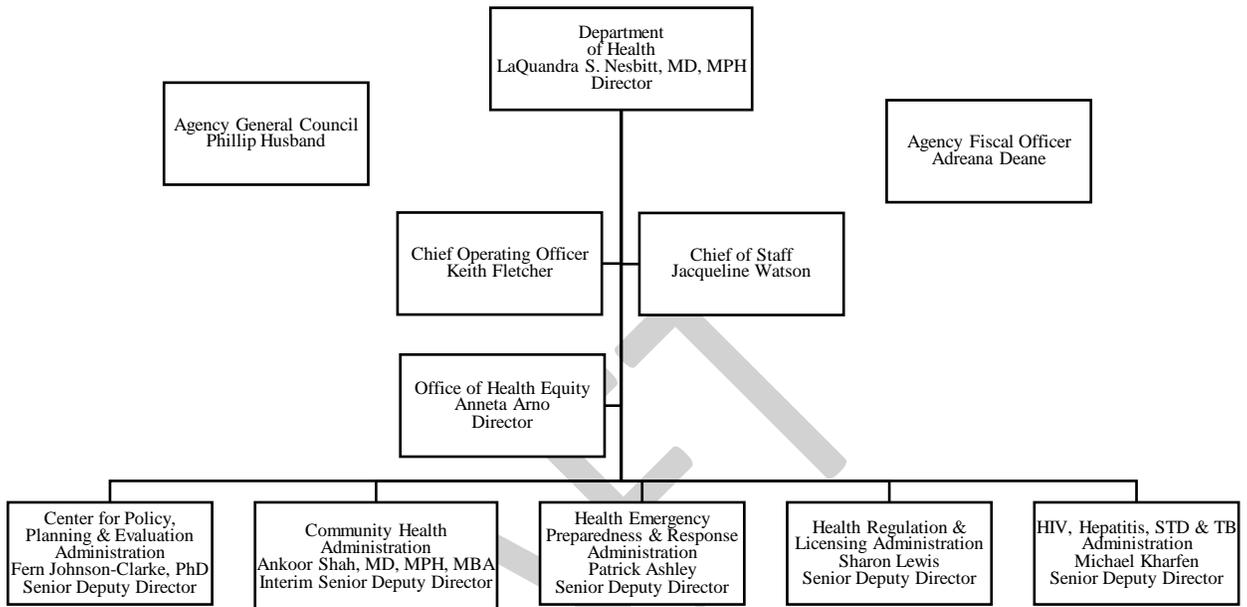
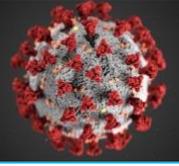


Figure 4.



- B.** Describe how your jurisdiction will plan for, develop, and assemble an internal COVID-19 Vaccination Program planning and coordination team that includes persons with a wide array of expertise as well as backup representatives to ensure coverage.

In May 2020, Immunization and Emergency Preparedness Planning program staff assembled to begin planning for the District’s COVID-19 vaccination efforts. In June, this team began meeting bi-weekly to discuss planning for three districtwide efforts related to vaccination – 1) improving routine childhood vaccinations; 2) implementing a seasonal influenza (flu) campaign; and 3) initiating COVID-19 vaccination planning. The same staff now comprise the COVID-19 Vaccination Planning and Coordination Team, in conjunction with internal staff from the DC Health Community Health Administration, Health Regulation and Licensing Administration, Center for Policy Planning and Evaluation, and the Office of the Director (including the Office of Health Equity and the Office of Communications and Community Relations). The COVID-19 Vaccine Planning and Coordination Team includes Subject Matter Experts (SME) in emergency management, immunization science, IT systems, pandemic planning, public health immunization policy, disease surveillance, and communications. Team members are charged with reviewing best practices in their respective disciplines; sharing updates and tasks within their respective administrations; and communicating with external stakeholders, such as the District’s Health



and Medical Coalition, the District's immunization coalition (ImmunizeDC), DC Primary Care Association, and DC Hospital Association. Based on lessons learned in the early phases of the District's COVID-19 response and Emergency Operation Center operations, backup representation in each discipline/SME area has been identified and a system of communication and information exchange has already been established.

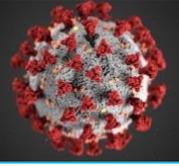
- C. *Describe how your jurisdiction will plan for, develop, and assemble a broader committee of key internal leaders and external partners to assist with implementing the program, reaching critical populations, and developing crisis and risk communication messaging.*

DC Health is using its current public health network to identify partners to support COVID-19 vaccine planning. The DC Community Health Needs Assessment (CHNA) released in 2019 utilized a diverse network of community partners that are connected to critical populations. The 2019 CHNA was a product of a multi-sector collaboration of health care providers, institutions, and stakeholders, who helped promote desired health outcomes and used results to identify assets within the community to support achievement of identified outcomes. The release of this report in advance of COVID-19 helped identify unique opportunities and community resources for addressing health equity and needs of critical populations.

DC Health and Medical Coalition

The DC Health and Medical Coalition (HMC) provides coordination among various healthcare stakeholders to include hospitals, skilled nursing facilities, health centers, governmental, non-governmental, local, and federal agencies in the District to enhance emergency preparedness planning and response. The DC HMC is the overarching coordination entity for healthcare preparedness and response activities in the District. The DC HMC was established to foster partnerships with government agencies, healthcare providers, and community partners to promote and coordinate a unified response to emergencies in the District of Columbia. The overall goal of the DC HMC is to ensure the sustainability of a robust and resilient healthcare system that can adequately prepare for, respond to, and recover from public health and healthcare threats. The DC HMC achieves this goal through strengthening partnerships with various healthcare facility types (especially those that serve vulnerable populations), building its evaluation and technical assistance capacity, and fostering coordinated and inclusive planning, training, and exercise based on data and evidence-based practices.

DC Health engaged the members of the DC HMC early on in the vaccination planning process. In anticipation of a tiered prioritization of vaccination, engagement with the DC HMC began with discussions on current vaccination endeavors and priorities, particularly as they relate to influenza. During an August 2020 meeting, members detailed their current plans for influenza vaccination, including: coverage rates, whether or not the influenza vaccine is required for the staff of their facility, how facilities track employee immunizations, and initial thoughts regarding preparations for COVID-19 vaccination. In September 2020 a survey was distributed to DC HMC members to formally assess the following: requirement of an annual influenza vaccine for staff, an employee health program that tracks staff immunizations, initial thoughts on whether or not



the facility would mandate a COVID-19 vaccine for their staff, the number of employees at each facility (including those that fit the Phase 1-A description in this plan), and their overall capability and capacity to provide a variety of possible COVID-19 vaccine products to their staff. In October and November 2020, the District's COVID-19 Vaccine Group has had continuous engagement and partnership with the HMC for initial vaccine allocation, distribution, and Phase 1 administration.

Immunize DC

ImmunizeDC's is a multi-sector, community-based coalition of immunization stakeholders and other health care professionals whose goal is to reduce vaccine preventable diseases in the District of Columbia. The coalition is comprised of membership from the public and private sectors, including health care systems and facilities, community-based organizations, the educational system, non-profit organizations, pharmacies, and pharmaceutical company representatives. ImmunizeDC will play an active role in facilitating education and messaging through these various networks for providers, and the general public through the implementation of the COVID-19 Vaccine Plan.

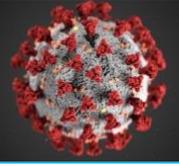
Scientific Advisory Committee

The DC Health Scientific Advisory Committee for the Development and Implementation of a Safe, Effective, and Equitable COVID-19 Vaccine Distribution Program in the District of Columbia, has been established to advise the Director of DC Health on:

- 1) Effective strategies to communicate information about vaccine safety and effectiveness, and promote confidence within the District for the COVID-19 vaccine.
- 2) Messaging and outreach strategies.
- 3) Promoting vaccine confidence among communities disproportionately impacted by COVID-19 by race/ethnicity, geography, age group, and setting (e.g., long-term care facilities).

About two-thirds of this committee is comprised of local District scientists, clinicians, and researchers with clinical trial expertise. The remaining one-third of this committee is comprised of local District community leaders from faith-based institutions, senior citizen coalitions, or racial and ethnic minority associations.

This committee meets virtually every 2-3 weeks and will continue at a regular cadence as determined the phase of the COVID-19 Vaccine implementation. This committee will stay active until appropriate population level immunity for SARS-CoV-2 is reached. All meetings are open to the public.



- D.** *Identify and list members and relevant expertise of the internal team and the internal/external committee.*

Vaccine Planning and Coordination Team (Internal)

Patrick Ashley – Health and Medical Branch Chief
Dr. Ankoor Shah – COVID-19 Vaccine Group Chief
Marie-Claire Brown – Public Health Policy
Heather Burris – COVID-19 Vaccine Team Lead and SME
Jacquelyn Campbell – Vaccine Storage and Handling
Donna Davidson – Immunization Program Manager and Vaccine Operations
Dr. Anitra Denson – Data and Evaluation
Ousman Jobe – IIS and Related Data Systems
Jacob Mbafor – Provider Engagement, Vaccine Ordering
Millicent Mike – Communication and Public Relations
Dr. Kofi Onuwah – Health Regulations
Courtney Logal – Health and Medical Vaccine Planning
Lindsay Schultz – Emergency Management
Todd Young – IT Interface and Integration

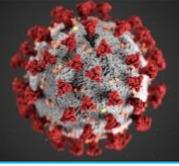
Scientific Advisory Committee (Internal/External)

DC Health Staff

Dr. LaQuandra S. Nesbitt, Director of DC Health, Committee Chair
Patrick Ashley, DC Health, Health and Medical Branch Chief
Dr. Ankoor Shah, DC Health, COVID-19 Vaccine Group Chief
Dr. Kimberly Henderson, DC Health, Public Information Officer
Heather Burris, COVID-19 Vaccine Group Team Lead and SME

Clinician and Scientist Members

- Dr. Andrea Anderson – Chair, DC Board of Medicine
- Dr. Melissa Clarke – Physician Consultant, 3M Health Information Systems and Member, Black Coalition Against COVID-19
- Dr. Millicent Collins – Board Member, The Medico-Chirurgical Society of the District of Columbia and Assistant Professor of Pediatrics, Howard University College of Medicine
- Dr. Roberta DeBiasi – Chief of Pediatric Infectious Diseases, Children’s National Hospital
- Dr. Melissa Fries – Chair, Women’s and Infant’s Services, Medstar Washington Hospital Center
- Dr. Alan Greenberg – Professor and Chair of the Department of Epidemiology and Biostatistics, GWU Milken Institute of Public Health and Professor of Medicine and of



Microbiology, Immunology and Tropical Medicine, GWU School of Medicine and Health Sciences

- Dr. Elmer Huerta – Clinical Professor of Medicine, George Washington Medical Faculty Associates
- Dr. Tamara McCants – Chair, Board of Pharmacy and Director of Residency Programs and Practice Transformation, Howard University College of Pharmacy
- Dr. J. Desiree Pineda – President of the Medical Society of the District of Columbia
- Dr. Pamela Riley – Medical Director, DC Department of Health Care Finance
- Dr. Marc Siegel – Associate Professor of Medicine, GWU School of Medicine and Health Sciences

Community Leadership Members

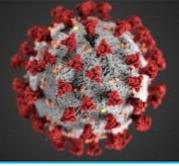
- Reverend Dr. Kendrick Curry – President, District of Columbia AARP and Pastor, Pennsylvania Baptist Church
- Lupi Quinteros-Grady – President and CEO, Latin American Youth Center
- Rhonda Hamilton – Ward 6 ANC Commissioner (6D06)
- Reverend Dexter Nutall – Pastor, New Bethel Baptist Church

Special Advisor

- Dr. Nicole Lurie – Former Assistant Secretary of Preparedness and Response, US Department of Health and Human Services and Clinician, Bread for the City

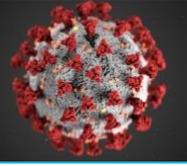
DC Health and Medical Coalition (External)

- DC Department of Health
- DC Hospital Association
- DC Health Care Association
- DC Primary Care Association
- DC Fire and EMS
- Office of the Chief Medical Examiner
- Homeland Security and Emergency Management Agency
- Bridgepoint Hospital – Capitol Hill
- Bridgepoint Hospital – National Harbor
- Children’s National Hospital
- HSC Pediatric Center
- Medstar National Rehabilitation Hospital
- Medstar Washington Hospital Center
- Medstar Georgetown University Hospital
- Sibley Memorial Hospital
- United Medical Center
- George Washington University Hospital
- Howard University Hospital
- Psychiatric Institute of Washington
- St. Elizabeth’s Hospital



ImmunizeDC Coalition (External)

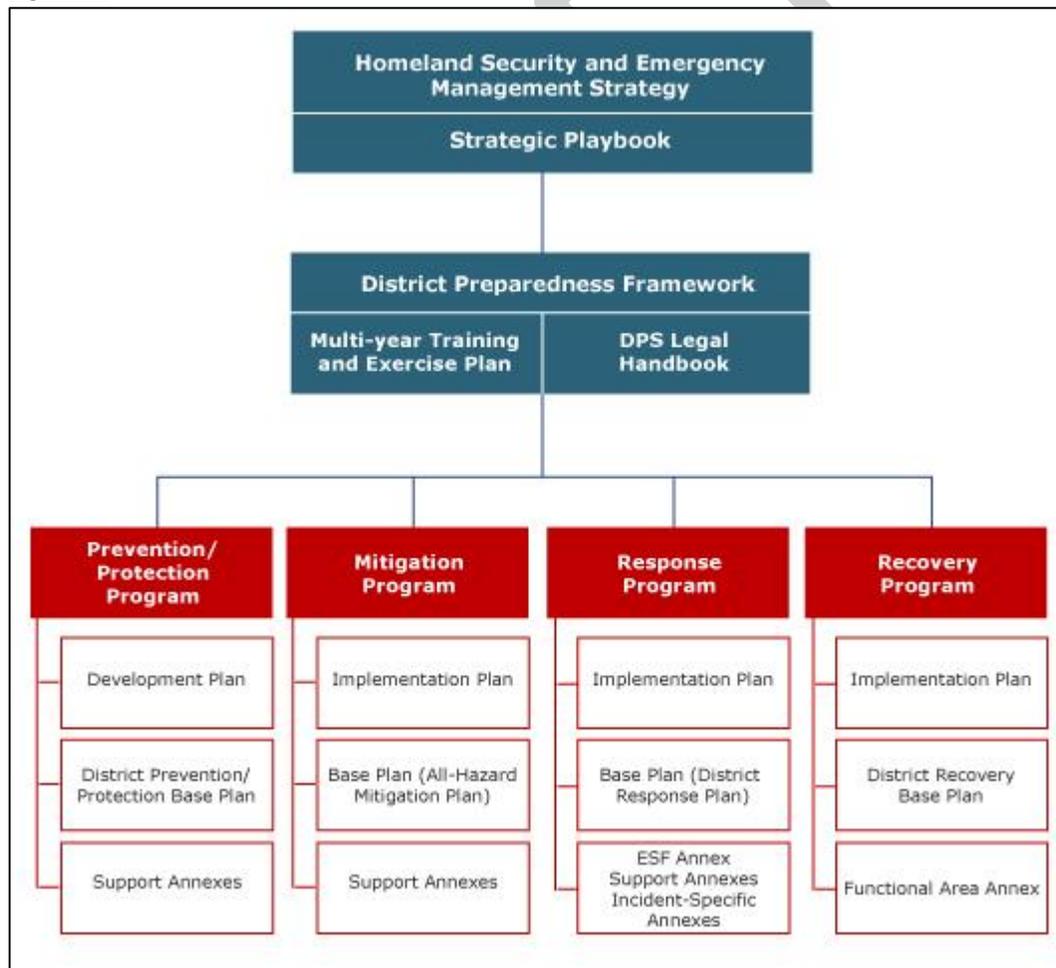
- American Academy of Pediatrics
- American Academy of Pediatrics, D.C> Chapter
- American Cancer Society
- American Pharmacist Association
- AmeriGroup District of Columbia
- AmeriHealth Caritas District of Columbia
- Carefirst Blue Cross and Blue Shield
- Children's National Hospital
- Community of Hope
- Core Health And Wellness Centers
- DC Health and Wellness Center
- DC Health Care Finance
- DC Public Charter School Board
- DC Public Schools
- Elaine Ellis Center of Health
- Families USA
- George Washington University School of Public Health
- Georgetown Day School/National Association of School Nurses
- Georgetown University
- Grubbs Pharmacy
- GlaxoSmithKline
- House of Ruth
- Howard University Hospital
- HSC Health Care System
- Kaiser Health
- March of Dimes
- Medico Chirurgical Society and National Medical Association
- Medical Faculty Associates (GWU)
- Merck
- National Association of County and City Health Officials
- Office of the State Superintendent of Education
- Pfizer
- Qlarant
- Sanofi Pasteur
- United Planning Organization
- Unity Health Care
- Walgreens

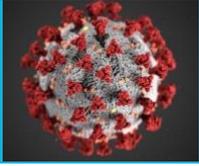


E. Describe how your jurisdiction will coordinate efforts between state, local, and territorial authorities.

The District of Columbia is uniquely geographically positioned adjacent to Maryland and Virginia, which together make up the National Capital Region. As was previously stated, in July 2019, DC participated in the National Capitol Region’s Medical Countermeasure, Point of Dispensing Full-Scale Exercise. Thus, emergency preparedness structure is regional in nature. During a pandemic, DC Health has specific emergency responsibilities in addition to normal day-to-day activities. General responsibilities for all federal, regional, District agencies, and non-governmental organizations (NGO) that support District emergency operations are contained in the DC Homeland Security and Emergency Management Agency (HSEMA) District Preparedness Framework (Figure 4). COVID-19 meetings currently taking place within this established structure will continue, with a broader focus on COVID-19 vaccine planning and distribution.

Figure 4.





Additionally, DC Health participates in regular regional meetings via the Metropolitan Washington Council of Governments, CDC, and HHS – including Region 3 Vaccine Task Force forums that began in August 2020. Throughout this pandemic response, DC Health has been in constant engagement and communication with the Virginia Department of Health and Maryland Department of Health.

- F.** *Describe how your jurisdiction will engage and coordinate efforts with leadership from tribal communities, tribal health organizations, and urban Indian organizations.*

The District does not have any known tribal communities, tribal health organizations, or urban Indian organizations in its jurisdiction.

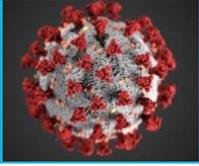
- G.** *List key partners for critical populations that you plan to engage and briefly describe how you plan to engage them:*

Key partners, who will support critical population efforts, are listed in Table 1, which include District Government agencies and Non-Governmental organizations. DC Health regularly coordinates with these entities to integrate public health programs and policies within their institutions, including seasonal influenza vaccination initiatives. We know the COVID-19 pandemic has disproportionately affected District seniors, those with chronic medical conditions, and racial and ethnic minorities. Additionally, this pandemic has highlighted the crucial role of our healthcare delivery infrastructure and workforce to meet the medical needs of District residents. Therefore, the partners have been identified with these details in mind.

DC will also engage its federal agency partners, including the Department of State, Department of Defense, Veteran Affairs, and Bureau of Prisons, for which allocations (direct) are known. DC Health has also been in contact with federal agencies to discuss distribution for their employees who are residents of the District or work within the District.

Table 1. District Government and Non-Government Agencies Roles & Responsibilities in COVID-19 Vaccine Planning

District Government Agency	Potential Roles and Responsibilities
DC Department of Behavioral Health (DBH)	<ul style="list-style-type: none"> ▪ Provides behavioral health services, as requested, for individuals with behavioral health vulnerabilities.
DC Office of Disability Rights (ODR)	<ul style="list-style-type: none"> ▪ Provides guidance to support those with access and functional needs. Provides guidance on accommodations and Americans with Disabilities Act (ADA) requirements.
DC Department of Human Services (DHS)	<ul style="list-style-type: none"> ▪ Provides guidance to support those served by DHS, including the homeless.
DC Department on Aging and Community Living	<ul style="list-style-type: none"> ▪ Provides services to seniors.

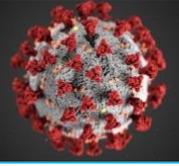


Department of Corrections (DOC)	<ul style="list-style-type: none"> Provides vaccination services to staff and inmates of the prison, and creates linkages to community-based supports for persons recently released/returning citizens.
DC Homeland Security and Emergency Management Agency (HSEMA)	<ul style="list-style-type: none"> Coordinates the overall response to emergencies and disasters. Provides 24-hour emergency operations center capabilities. Requests SNS assets at the request of the Mayor. Houses the Washington Area Fusion Center that provides situational awareness.
DC Fire and Emergency Medical Services (FEMS)	<ul style="list-style-type: none"> Supports emergency medical services transportation needs related to a distribution and dispensing operation. Provides emergency medical services staff to support dispensing operations.
Non-Government Agency	Potential Roles and Responsibilities
ImmunizeDC	<ul style="list-style-type: none"> Serve as immunization SMEs, and utilize stakeholder networks to address vaccine confidence, and promote DC Health messaging to the public.
Health Systems and Hospitals	<ul style="list-style-type: none"> Continue operations to provide health care for persons impacted by the flu, COVID-19, and other illnesses. Ensure readiness of facility to support the receipt, administration, and reporting of vaccine for staff during Phase 1 and 2.
Federally Qualified Health Centers	<ul style="list-style-type: none"> Ensure readiness of facility to support the receipt, administration, and reporting of vaccine for staff during Phase 1 and 2.
Pharmacies	<ul style="list-style-type: none"> Serve as vaccinators for staff at long-term care facilities in Phase 1, and the broader public in Phase 2.
Long-term care facilities	<ul style="list-style-type: none"> Ensure readiness of facility to support the receipt, administration, and reporting of vaccine for staff during Phase 1, and continuity of vaccine administration beyond Phase 2.
Religious institutions	<ul style="list-style-type: none"> Communicate messaging and updates to their congregations on vaccine safety, availability, and access.
Community Based Organizations	<ul style="list-style-type: none"> Promote DC Health messaging on vaccine safety and availability and access for all populations in all areas of the city.

Section 3: Phased Approach to COVID-19 Vaccination

A. Describe how your jurisdiction will structure the COVID-19 Vaccination Program around the three phases of vaccine administration:

Due to the evolving planning assumptions for the COVID-19 Vaccine, DC Health is using a three phased approach, as outlined by CDC. DC Health continues to engage with stakeholder groups that will support vaccine administration for the critical populations identified for Phase 1, as outlined in Section IV of this plan.



In addition to the DC's geographical uniqueness, there is a high number of individuals that work in the District but do not live in the city. This includes but is not limited to persons employed in clinical settings, schools, and District and federal government agencies. The District is currently in Phase 2 of its Reopening. As COVID-19 epidemiologic data is used to drive the reopening metrics, at the time when the COVID-19 vaccine becomes available, the number of persons that work in the District will exceed its total population of an estimated 705,000. Therefore, while DC will implement a plan based on the three phased approach, as outlined by the CDC (Figure 5), the **driver will be the number of individuals within settings and not the number of residents**. This approach is most suitable for our jurisdiction, as was learned from H1N1 and review of standards of practice for vaccine allocation during pandemics. It would have the greatest impact on combatting COVID-19 and addressing the critical workforce, comprised of residents from Maryland and Virginia, for which DC is responsible during this pandemic.

Phase 1: Potentially Limited Doses Available

While implementing Phase 1 of the vaccine distribution plan, DC Health will continue SARS-CoV-2 mitigation and containment strategies, in addition to active influenza surveillance. Epidemiologic data from ongoing surveillance activities will be used to provide context regarding the critical populations to serve as priority groups for vaccinations in Phase 1 (and remaining groups during Phase 2), including shifts in data trends that may impact identified target groups.

Given the limited number of doses expected in Phase I, provider allocations will be based on:

- ACIP recommendations
- Input from the District's Scientific Advisory Committee
- Input from Bioethicist Daniel P. Sulmasy, MD, PhD; Andre' Hellegers Professor of Biomedical Ethics and Acting Director of the Kennedy Institute of Ethics at Georgetown University.
- Estimated number of doses allocated to the jurisdiction and timing of availability
- Settings where persons representing the critical workforce are employed, and that have been disproportionately impacted by COVID-19
- Populations served by vaccination providers and geographic location
- Vaccination provider site vaccine storage and handling capacity
- Minimal potential for wastage of vaccine, constituent products, and ancillary supplies
- Other local factors identified through the planning process

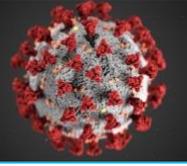
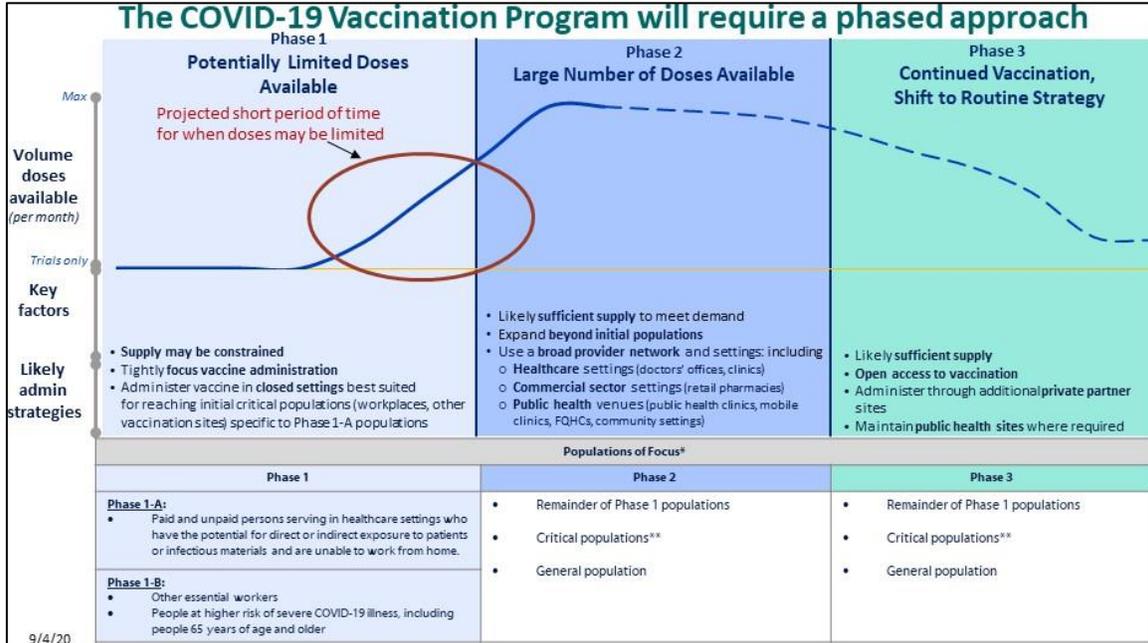


Figure 5.



DC is considering the *National Academies of Science, Engineering, and Medicine Committee on Equitable Allocation of Vaccine for the Novel Coronavirus's* Framework for equitable allocation of COVID-19 vaccine on current evidence, recognizing its uncertainties and the need for flexibility as evidence emerges and medical realities changes. The framework's foundational principles guide its goal, allocation criteria, and allocation phases (Figure 6).

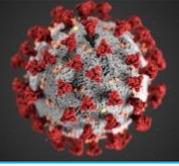
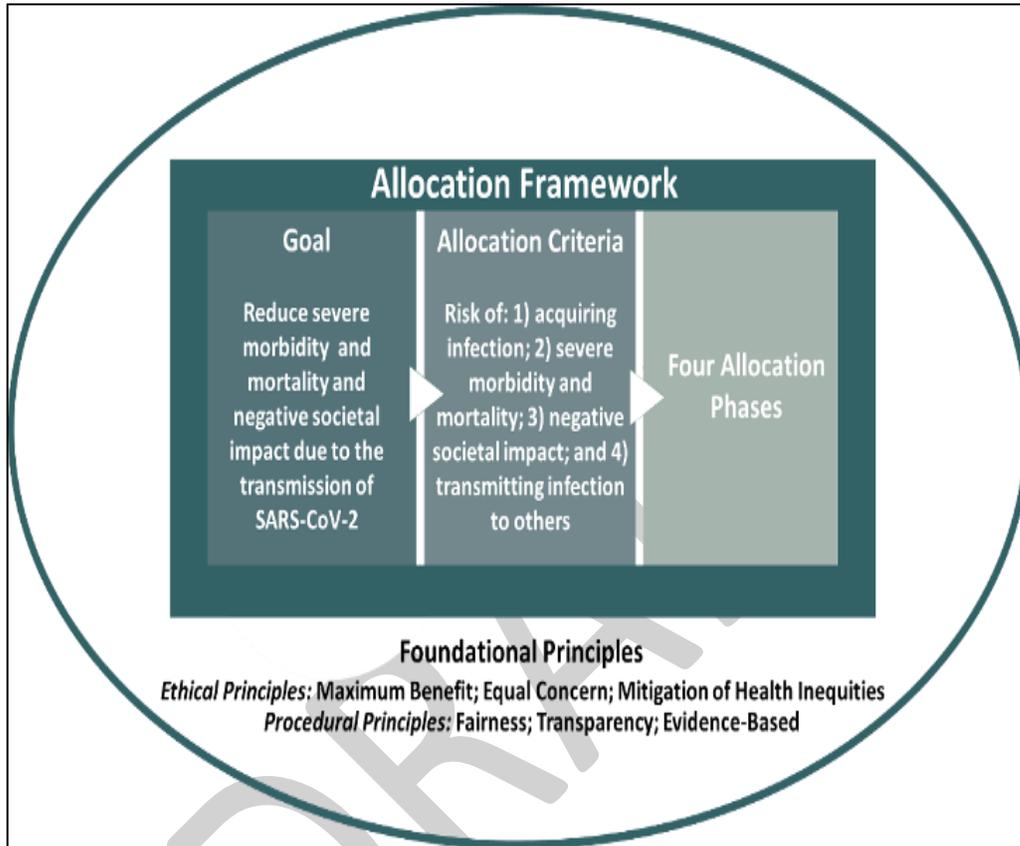
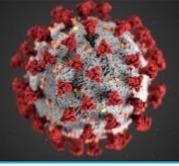


Figure 6. Major elements of the National Academy of Medicine’s framework for equitable allocation of COVID-19 vaccine.





Phase 2: Large Number of Doses Available, Supply Likely to Meet Demand

The DC COVID-19 Vaccine Planning Group will lead the planning for logistical scenarios related to vaccine availability, procurement, and supply management. This will be in coordination with the District's Emergency Operations Center, DC's Health and Medical Coalition, and key agency partners such as the Homeland Security and Emergency Management Agency.

DC Health will manage inventory and ordering through the new IIS for enrolled providers, who are authorized to administer the COVID-19 Vaccine. The new IIS will also support vaccine management and distribution and redistribution, as needed. The various data dashboards will direct the Planning Team to areas of greatest need, which can be communicated to the public by linkages to facilities administering vaccines in their respective areas. If there are still vaccination gaps or pockets of need, mass clinics can be activated.

The first recommendation for the public is to utilize their medical home since the District has high access to primary care across all eight Wards and high health insurance coverage. However, DC recognizes the vaccine storage and handling barriers for many providers. Providers who enrolled as COVID-19 vaccinators will be encouraged to register for vaccinefinder.org in advance of Phase 1.

Phase 3: Likely Sufficient Supply, Slowing Demand

Data monitoring and reporting will continue to drive vaccine allocation and access for Phase 3. As more regular supply of vaccine becomes available, providers who are registered for vaccinefinder.org, will have their locations published to inform residents of locations for available vaccine. This will be in combination with focused public health messaging to communities that have been disproportionately affected by the COVID-19 pandemic but who also have high rates of vaccine hesitancy. Lessons learned from Phases 1 and 2 will support the planning and distribution of a future pediatric vaccine and vaccine for pregnant women.

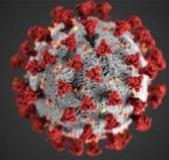
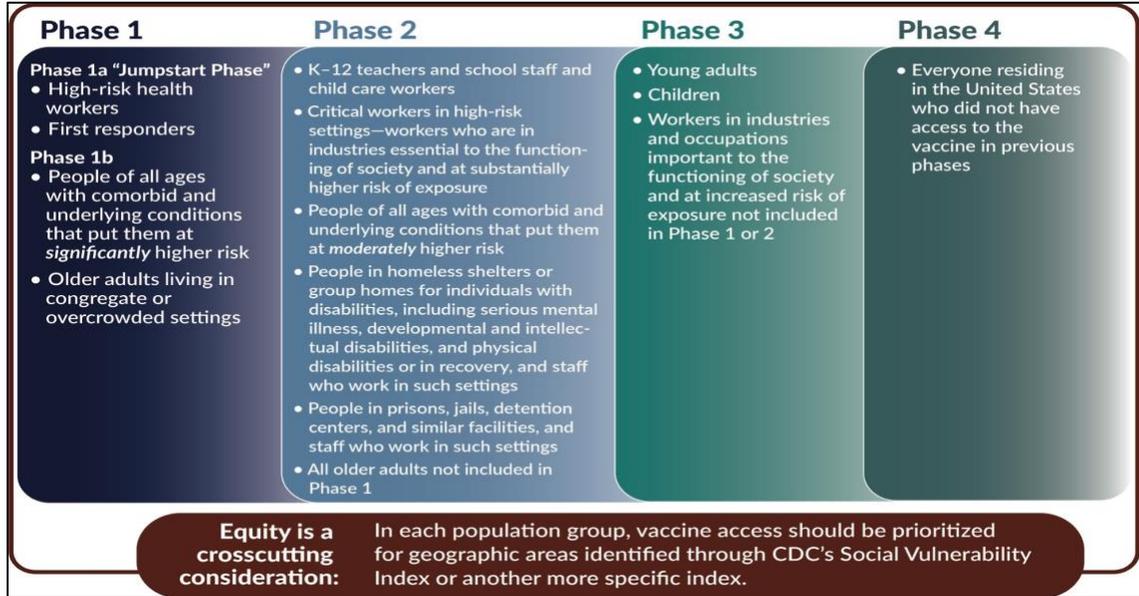
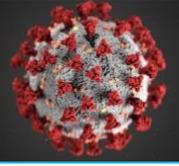


Figure 7. A Proposed allocation for consideration for vaccine distribution to ensure equity.



Source: National Academies of Sciences, Engineering, and Medicine 2020. Framework for Equitable Allocation of COVID-19 Vaccine. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25917>.

DRAFT



Section 4: Critical Populations

A. Describe how your jurisdiction plans to: 1) identify, 2) estimate numbers of, and 3) locate (e.g., via mapping) critical populations. Critical population groups may include:

The following populations will be highest priority:

- **Phase 1-A:** Paid and unpaid people serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials and are unable to work from home. This will also include first responders.
- **Phase 1-B:** People who play a key role in keeping essential function of society running and cannot socially distance in the workplace (e.g., healthcare personnel not included in Phase 1-A, emergency and law enforcement personnel not included in Phase 1-A, food packaging and distribution workers, teachers/school staff, childcare providers), and people at increased risk for severe COVID-19 illness, including people 65 year of age or older.

DC's geographic location is distinctive in that, though it is its own separate jurisdiction, there is significant movement of the population between Maryland, Virginia and the District. There are also a significant number of people who work in the District and live in either Maryland or Virginia, and vice versa. Despite their state of residence, they are part of the necessary workforce and critical infrastructure that keeps the District functioning. **The District will count those who reside in another state but work in District healthcare facilities as part of the essential personnel who will require a COVID-19 vaccination in the District.** For example, of the over 30,000 individuals who work within the District's acute care hospitals, 70-75% reside outside of the District.

DC Health continues to work with the CDC and HHS Operation Warp Speed, who in turn is in communication with key federal agencies (VA, DOD, DHS, BOP, IHS) regarding their estimated vaccine allocations for their employees. It is expected that these agencies will include in their COVID-19 vaccination plans, requested allocations to serve their employees. The District will continue working with Maryland and Virginia to ensure there are no gaps in identification, estimation, and allocation for Federal workers; many of whom live within the National Capital Region. The numbers below do not reflect the federal employees.

The estimate of Critical Workforce and Populations for Phase 1 of COVID-19 Vaccine Distribution was created using available information from DC government agencies, local community partners, CDC's Behavioral Risk Factor Surveillance System (BRFSS) for the District, DC Health's Health Regulation and Licensing Administration, and DC's Health and Medical Coalition Healthcare Workforce Survey (Table 2).

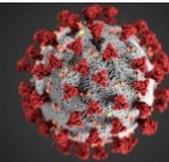
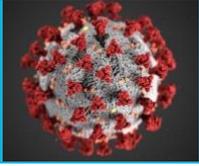


Table 2. Estimate of Critical Workforce and Populations for Phase 1 of COVID-19 Vaccine Distribution

Category	Population Group	Estimates
Phase 1a		
	Total Full and Part Time Hospital Staffing	33,850
	Nursing and Residential Care Facility Employees	14,810
	Outpatient Providers and Ancillary Care Providers	11,445
	Home Health Providers	8,115
	Health Care Providers in Long-Term Care Facilities (LTCF)	7,860
	Pharmacists and Pharmacy Technicians	5,300
	Emergency Services & Public Safety (e.g., Fire/EMS)	3,170
	Front-Line Public Health Personnel	550
	Phase 1a Total	85,100
Phase 1b		
	DC Government Critical Infrastructure Personnel	3,800
	Law enforcement and Public Safety	10,500
	Department of Corrections Residents and Staff	2,921
	Residential Care Community Residents	1,220
	Nursing Home Residents	1,260
	Homeless, Transitional Housing Residents	6,521
	Grocery Store Employees	9,590
	Childcare Providers and Staff	7,000
	School Teachers and Staff	20,000
	Persons 65 years and older	84,960
	Adults 19 - 64 with High Risk Conditions	163,000
	Phase 1b Total	310,772

For Phase 1-B, in addition to the workers necessary to keep the District running, it is important to protect our residents at the highest risk of severe illness. As of November 20, 2020 there were 670 deaths due to COVID-19 in the District. Of those deaths, 546 (81%) were persons 61 or older. The greatest fatality rates were among residents of Skilled Nursing Facilities and Assisted-Living Residencies with mortality rates of 23% and 28%, respectively.



Current approach for the following populations is to capture them through to above mentioned settings:

- People who are under- or uninsured
- People from racial and ethnic minority groups
- People with disabilities

Nearly all District residents either have private health insurance or are eligible for public health insurance coverage. For those persons who are uninsured, DC Health will utilize partnerships with the D.C. Primary Care Association (via the established DC’s Health and Medical Coalition) and the D.C. Department of Human Services in order to identify and coordinate care for this relatively small population.

The District of Columbia does not have the following within our community:

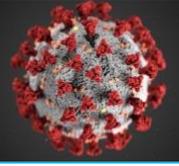
- People from tribal populations
- People living in rural environments

B. Describe how your jurisdiction will define and estimate numbers of persons in the critical infrastructure workforce, which will vary by jurisdiction.

The District sent a supplementary workforce survey to members of the District’s Health and Medical Coalition to support the estimates provided above and help identify staff of high impact within an organization. Using this data combined with licensing data, local government workforce data, voluntary surveys, or other means such as data collection from the trade associations.

Total # of employees at all facilities that work in the <u>inpatient</u> setting and may have contact with patients	Total # of employees at all facilities that work in the <u>outpatient</u> setting and may have contact with patients	Total # of employees at all facilities that work in the <u>emergency</u> setting and may have contact with patients	Total # of employees at all facilities that work in a <u>high acuity</u> setting (e.g., ICU/HAI, NICU or OR) and may have contact with patients	Total # of employees are at increased risk of serious complications related to COVID-19
21950	10851	1407	4881	2714

DC Health estimated its medical and non-medical personnel working in the District (above) using these described tactics. Other critical infrastructure can be estimated in collaboration with the District’s Homeland Security and Emergency Management Agency (HSEMA) and other local government agencies.



- C.** *Describe how your jurisdiction will determine additional subset groups of critical populations if there is insufficient vaccine supply.*

Within the Phase 1-A population of 113,840, the District has engaged the Scientific Advisory Committee and Bioethicist Dr. Daniel Sulmasy from Georgetown University to help develop a strategy for sub-stratification of our Phase 1a population. The District will then develop guidelines and recommendations for providers and facilities to prioritize vaccination in this sub-group, if necessary. See Appendix A. for the strategy for sub-stratification of Phase 1a populations.

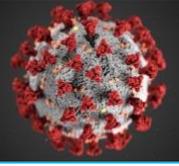
- D.** *Describe how your jurisdiction will establish points of contact (POCs) and communication methods for organizations, employers, or communities (as appropriate) within the critical population groups.*

During the COVID-19 response, the District has established points of contact with the above listed groups. Through the District's Health and Medical Coalition, DC Health has reliable points of contact with organizations representing many of the Healthcare Providers in the city –DC Hospital Association, DC Health Care Association (represents long term care industry), and DC Primary Care Association. The Coalition, through DC Health's Health Regulation and Licensing Administration (HRLA), has good standing relationships and communication with all licensed healthcare facilities in the District. HRLA will continue to serve as a source for tracking and communicating important information regarding the COVID-19 response and vaccination efforts. DC Health has also strengthened and maintained relationships with other critical partners such as Consortium of Greater Washington Area Colleges and Universities, District of Columbia Public Schools, Public Charter School Board, Department of Corrections, Department of Insurance, Securities, and Banking, DC Chamber of Commerce, and Department of Human Services. DC Health will continue to connect with these group and other critical infrastructure entities, as needed.

Section 5: COVID-19 Provider Recruitment and Enrollment

- A.** *Describe how your jurisdiction is currently recruiting or will recruit and enroll COVID-19 vaccination providers and the types of settings to be utilized in the COVID-19 Vaccination Program for each of the previously described phases of vaccine availability, including the process to verify that providers are credentialed with active, valid licenses to possess and administer vaccine.*

DC Health initially distributed the COVID-19 Vaccine Provider Agreement through the DC HMC. As detailed above in section 2C, this group includes all Phase 1a acute-care facilities where the greatest population of healthcare staff are employed. In the latter phases of general public distribution, DC Health will expand to include private healthcare facilities and providers who are not currently enrolled in either the Vaccines For Children (VFC) or Vaccines For Adults (VFA) Programs. These providers generally meet the following criteria:



- Health care institutions that have a large workforce who serve critically ill individuals – all acute care hospitals in DC,
- Long-term Care Facilities
- Federal institutions that are not directly served with supplies from the CDC
- Agencies that have critical workforce personnel
- DC Department of Corrections and Homeless shelters
- Pharmacies – Chain and Independent – who would be able to vaccinate critical workforce/employers that do not have the capacity to vaccinate their own people
- Community-based organizations - – who would be able to vaccinate critical workforce/employers that do not have the capacity to vaccinate their own people

Provider Recruitment and Enrollment

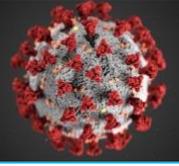
Provider recruitment will start by focusing on Tier 1 groups that are acute care facilities as prepositioned sites who are able to receive, store, handle, and administer vaccines. While the provider agreement will be available online and disseminated widely, the focus will be to verify and enroll the larger hospital systems with the intent that they can administer their staff and other healthcare workers in the city. For providers who have never before received vaccine through DC Health, we have developed a process map for onboarding providers.

Additionally, the District intends to create public-private partnerships for vaccine administration in addition to planning for government supported immunization. The District does not operate a direct-services health facility for the general public. As a result, we will participate in the private pharmacy partnership established by CDC to immunize residents of Long-Term Care Facilities. Furthermore, we have developed a partnership with Walgreens to be a prepositioned site where District government essential employees and possibly other Phase 1b vulnerable populations may be immunized through registration.

- B.** *Describe how your jurisdiction will determine the provider types and settings that will administer the first available COVID-19 vaccine doses to the critical population groups listed in Section 4.*

Health care facilities with the capacity to handle, store, and vaccinate their own staff will be among some of the first recipients of the vaccines.

Additionally, the District will be procuring resources to provide off-site vaccination to those in critical facilities that are not able to receive, handle, store and administer vaccines. The District has pre-identified sites that could be used to administer vaccine that does not require ultra-cold storage, and has also planned for these events to be scalable to accommodate several sizes of Point of Dispensing (POD) sites (small, medium, and large). It is anticipated that this will be a limited event in terms of the number of events and the frequency of events.



Due to the ultra-cold (-60 to -80 degrees Celsius) storage needs of the Pfizer developed COVID-19 vaccine, the sites that this vaccine is delivered to must have ultra-cold freezer capacity. Afterwards these sites will coordinate with the District to ensure Phase 1a population vaccination. DC Health will determine allocations of initial vaccine regardless of location they are stored.

Potential Pre-position sites for the Pfizer COVID-19 Vaccine:

1. George Washington University Hospital
2. Walgreens Community Pharmacy at 1117 Good Hope Rd SE
3. Howard University Hospital
4. Children's National Hospital
5. Medstar Washington Hospital Center
6. Medstar Georgetown University Hospital
7. Sibley Memorial Hospital
8. Kaiser Center for Total Health

The Moderna COVID-19 vaccine does not need ultra-cold storage. DC Health will still determine initial allocations and criteria for this vaccine's initial administration. However, the Moderna vaccine can be delivered to many more providers who have signed the Vaccine Provider agreement.

The Pfizer COVID-19 vaccine can be leveraged to vaccinate those healthcare workers part of larger institutions, whereas the Moderna vaccine can be leveraged to vaccinate those other healthcare workers through a broad-based multi-site access strategy.

- C.** *Describe how provider enrollment data will be collected and compiled to be reported electronically to CDC twice weekly, using a CDC-provided Comma Separated Values (CSV) or JavaScript (JSON) template via a SAMS-authenticated mechanism.*

VFC and VFA providers will continue to report using the current established protocols. The Program is currently working with a vendor to onboard users in a new IIS that is being implemented. In the interim, we have re-created the provider agreement as an online form in a database (Quickbase) that can be accessed publicly. As providers enroll and are verified, a CSV data file will be downloaded twice weekly to send to the IZ Data Lake at the required timelines. CDC required data elements are incorporated in all the systems that are being used, including the new IIS to capture enrollment information/data.

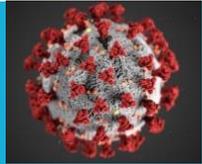
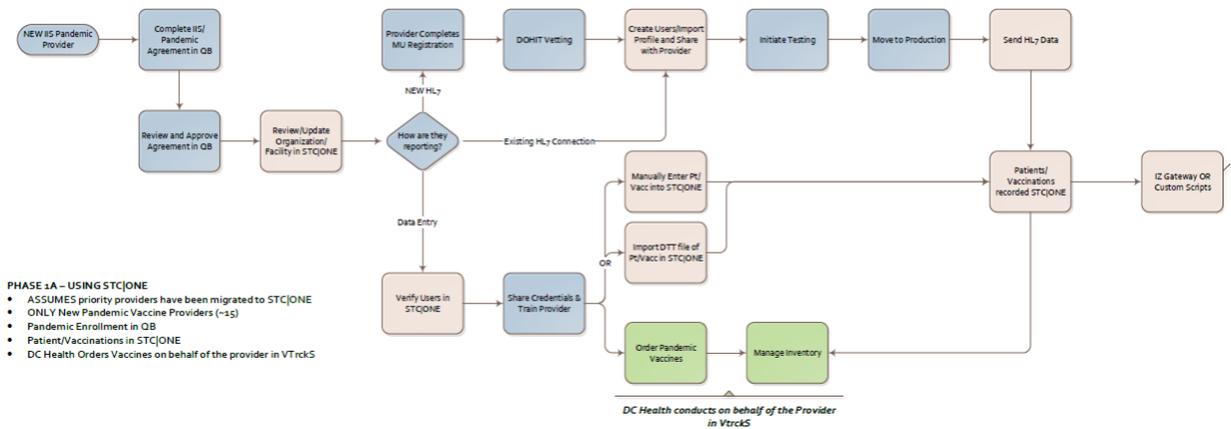


Figure 8.



D. Describe the process your jurisdiction will use to verify that providers are credentialed with active, valid licenses to possess and administer vaccine.

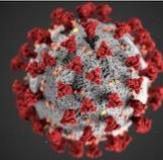
Licensing and credentialing of providers and healthcare facilities is maintained within DC Health. Information on licensing and credentials will be collected on the Provider Enrollment Form which will be verified with Health Regulatory and Licensing Administration records. Additionally, DC Health also verifies the List of Excluded Individuals and Entities (LEIE) to ensure that any licensed individual on the list does not participate in VFC and/or VFA.

E. Describe how your jurisdiction will provide and track training for enrolled providers and list training topics.

CDC and manufacturer resources will be used to train providers virtually and in-person. Specific courses such as You Call The Shots Modules on Vaccine Administration and Storage and Handling will be required for Primary and Backup Vaccine Coordinators prior to receiving vaccines, verified by the submission of a training certificate. A partial list of the potential trainings are listed in section 8 (Module 10, VPD Epi, etc.).

Training of COVID-19 vaccination providers will be provided through WebEx or other virtual communication tools. Training topics will include but not limited to:

- ACIP recommendations
- COVID-19 vaccine ordering, receiving, storage, and handling
- IIS/VAMS
- Vaccine administration
- Management of vaccine wastage, spoilage, temperature excursions



- Reporting adverse events to Vaccine Adverse Event Reporting System (VAERS)
- Emergency Use Authorization fact sheets, vaccine information statements (VISs)

DC Health will utilize educational materials developed by the CDC or develop local community-specific engagement materials.

Additionally, all providers will need to be trained in the new IIS. We have secured training as a component of our agreement with the vendor and there will be a series of offerings made available to all users of the new IIS.

- F.** *Describe how your jurisdiction will approve planned redistribution of COVID-19 vaccine (e.g., health systems or commercial partners with depots, smaller vaccination providers needing less than the minimum order requirement).*

DC Health's Immunization Program coordinates vaccine transfers among VFC and VFA providers to minimize wastage and vaccine losses. While it would be ideal to ship all vaccines to the point of usage or administration, we understand there would be a need for redistribution or repackaging due to minimum shipment quantity. We will track usage and inventory, and coordinate transfers between site by 1) assessing providers' ability to perform the transfer and if not feasible 2) actually assigning staff to do the transfers. The new IIS will be able to facilitate this process easier. For any site that is deemed a redistributor, a redistribution agreement will be signed and allocations divided by Immunization Program staff.

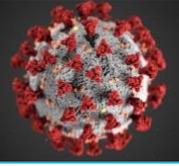
For small volume sites, vaccines will be shipped to a District government prepositioning storage location in the public health laboratory that is ready and being monitored. Staff who are trained to receive, handle, store, repackage and transport vaccines, will redistribute to those small vaccination sites, under strict cold chain control.

- G.** *Describe how your jurisdiction will ensure there is equitable access to COVID-19 vaccination services throughout all areas within your jurisdiction.*

While DC Health will distribute vaccines based on each facility's ability to handle, store, and administer vaccines, we will also plan to be equitable by ensuring vaccines are provided or redistributed to vulnerable and priority populations. For these populations, the public-private partnership may be of greatest resource for ensuring equitable access to vaccine. Provider surveys are being used to support sub-stratification within phase population groups, and the results will inform planning for onsite vaccinations to ensure equitable distribution.

- H.** *Describe how your jurisdiction plans to recruit and enroll pharmacies not served directly by CDC and their role in your COVID-19 Vaccination Program plans.*

DC Health has partnerships with several chain and independent pharmacies, who are currently linked with the DOCIIS and report vaccination data. Additionally, DC Health is engaging with a



consortium of independent pharmacies in order to onboard more pharmacies to the DOCIIS. Working in close collaboration with the DC Health Board of Pharmacy, we will share enrollment instructions and requirements for smaller chain or independent pharmacies and they will be eligible to order and receive vaccine. Pharmacies will be a focus for Phase 2 enrollment and vaccine distribution when more vaccine is available that is able to be stored under typical conditions. We will assess pharmacy location across the jurisdiction to ensure widespread access is available across the District.

Section 6: COVID-19 Vaccine Administration Capacity

- A.** *Describe how your jurisdiction has or will estimate vaccine administration capacity based on hypothetical planning scenarios provided previously.*

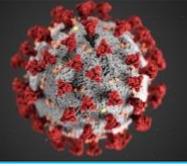
The vaccination capacity of providers affiliated with the VFC and VFA has been established. For new providers, the District will rely heavily on the provider profiles provided through the provider agreement. Additionally, and beyond Phase 1a providers, we will create a similar tool to assess a facility's ability to immunize their patient population in a specified period of time. Similar to the prepositioning questions for large acute care facilities, this will help us understand how to allocate vaccine when orders are requested. A facility's ability to receive, handle, store, and administer vaccines are critical components that would inform our jurisdiction's ability to allocate wisely. The ability to report usage would also be an important element to consider.

- B.** *Describe how your jurisdiction will use this information to inform provider recruitment plans.*

DC will prioritize its recruitment effort based on the results of the survey and providers targeted for Tier 1 settings, in Phase 1a and 1b. Providers that have the capacity to administer, store and handle the COVID-19 vaccines demonstrated by documentation of proper equipment and temperature monitoring devices, and trained staff will be given the vaccines first. We will provide technical assistance and assist other providers that are not presently ready to become ready.

Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management

- A.** *Describe your jurisdiction's plans for allocating/assigning allotments of vaccine throughout the jurisdiction using information from Sections 4, 5, and 6. Include allocation methods for populations of focus in early and limited supply scenarios as well as the variables used to determine allocation.*



Allocations of vaccine will be determined by sub-population estimates and dependent on the phased execution strategy. During phase 1, data on healthcare workers and facilities, and essential staff in the District collected through survey assessments, health licensing census, District government human resources information, and federally supported data such as the CDC's Behavioral Risk Factor Surveillance System (BRFSS) for the District. During phase 2, and as vaccine targets focus on the general population, residential population estimates and also data used to support flu vaccinations will be useful in planning allocations. As providers begin to enroll and complete the Provider Pandemic Agreement, data from Pandemic Profiles will be utilized to determine vaccine administration capacity within facilities.

One potential strategy to ensure there is limited double-counting by facilities will be to employ a vicinity restriction. This would allow providers to report profile data from previous encounters plus an excess of a certain percentage for the surrounding community. In parts of the city where there are frequent drug store retail locations, this will help account for transient populations between more than one facility.

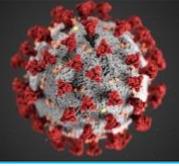
An important notation for the District will be to consider the daytime and nighttime population counts. Because DC supports the federal workforce, employees who travel into the city for daily activities must be factored into estimates. The daytime population during non-pandemic time swells upwards of 80% from the residential population. Including workforce estimates for the general population will be necessary to ensure adequate allocations and supply.

Another important consideration is to adequately capture home health clients. Again, for Phase 1, the **driver will be the number of individuals within settings, and not the number of residents.**

- B.** *Describe your jurisdiction's procedures for ordering COVID-19 vaccine, including entering/updating provider information in VTrckS and any other jurisdictional systems (e.g., IIS) used for provider ordering. Describe how you will incorporate the allocation process described in step A in provider order approval.*

Current Facilities/Users of CDC's Vaccine Tracking System (VTrckS)

Current providers with active Provider Identification Numbers (PINs) are registered in CDC's Vaccine Tracking System (VTrckS). To order vaccines prior to the launch of the new immunization information system, a VTrckS identity voucher on file for each user at a facility has been processed and approved by the CDC to access the Secure Access Management System (SAMS). It is recommended to have at least two users within a facility who can prepare a vaccine order in VTrckS from a preset vaccine catalog determined by the Immunization Program Vaccine Manager. After the launch of the new immunization information system, all vaccine orders will take place directly within the IIS. Former VTrckS users will receive the same level of access to place orders in the new IIS.



New Facilities/Users

DC Health staff will add new Providers to VTrckS but place orders on their behalf until the new IIS is launched. At that time all new and current providers and users will receive training on ordering in the new IIS. New providers will have completed the COVID-19 Vaccine Provider Agreement prior to issuance of a PIN.

For current and new provider facilities, allocations will be carefully decided upon based on the Phase 1a distribution strategy. Prepositioned facilities will likely receive the bulk of the first vaccine available based upon storage capacity and the number of staff they are able to vaccinate in 10 days. The COVID-19 Vaccine Planning Team will map out which facilities will receive vaccine and assign other healthcare staff to those facilities who have designated their status as Open point of dispensary sites. Vaccine orders will be reviewed and approved by Immunization Program staff for consistency with the District allocation strategy. Additionally, use of the Provider Profile form, available previous influenza vaccine order data, and readiness to receive and properly store vaccine are all factors pending order approval.

The new IIS is expected to go live in phases with provider ordering being the first phase of functionality. While it is difficult to predict the availability of the first vaccine, we have created a contingency plan in the event that vaccine is available before the new IIS is available for users. Until the go-live date, program staff will create a COVID-19 vaccine order form where providers will manually request vaccine, and program staff will place orders on behalf of providers in VTrckS. Simultaneously, all providers and users will be trained to order vaccine in the new IIS so that they are ready and able to transition when the functionality is available.

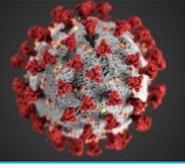
Because DC Health is ordering on behalf of providers, verifying accurate ordering and shipping information for each location will be the responsibility of the team. This is a routine function of the Immunization program staff. Addresses will be verified against enrollment data and reviewed again with each paper vaccine order form submission.

C. *Describe how your jurisdiction will coordinate any unplanned repositioning (i.e., transfer) of vaccine.*

Currently, program staff receive and review all vaccine return requests on a case by case scenario. If an organization has multiple facilities, program staff allow the organization to redistribute vaccine amongst the facilities within the organization where the need or capacity to administer vaccine can occur. If a vaccine return request cannot be redistributed within another organizational facility, program staff will identify another provider facility who is able to use the vaccine and will provide technical assistance to support the transfer safely. This same process will be supported and managed within the new IIS, without restrictions for redistribution within the same facility.

D. *Describe jurisdictional plans for monitoring COVID-19 vaccine wastage and inventory levels*

Currently, DC Health receives and review vaccine wastage notices from providers. On occasion, certain providers have the ability to directly enter wasted vaccine in VTrckS and program staff



review and reconcile as necessary. Within the new immunization information system, all vaccine administered is tracked and can be identified as wasted when provider facility staff reconcile their inventory monthly.

Because of the fragility of the first doses of the Pfizer vaccine, inventory and wastage will be monitored very closely by DC Health. All Providers are required to report vaccine inventory in Vaccine Finder and this will help to see if doses have been wasted at weekly or more frequent intervals.

DC Health also routinely reviews vaccine inventory prior to approving an order. Restrictions are set such that a new inventory must be added within two weeks of the date of order or else the order cannot be submitted. Inventory is reviewed to identify usage trends and reconciliation with vaccine administration reports. DC Health also reviews recent submissions of temperature monitoring reports to verify that equipment is maintaining the cold chain prior to approving a vaccine order. These steps may become automated reports created by the new immunization information system.

Section 8: COVID-19 Vaccine Storage and Handling

- A.** *Describe how your jurisdiction plans to ensure adherence to COVID-19 vaccine storage and handling requirements, including cold and ultracold chain requirements, at all levels.*

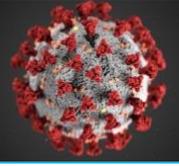
DC Health will utilize existing guidance on vaccine storage and handling, with modifications made based on requirements for final, available vaccines.

Individual provider location

The vaccine cold chain is a temperature-controlled environment used to maintain and distribute vaccine in optimal conditions. The cold chain begins with the cold storage unit at the manufacturing plant, extends through transport of vaccines to the distributor, delivery to and storage at the provider facility, and ends with administration of vaccine to the patient. Appropriate storage and handling conditions must be maintained at every link in the cold chain.

The DC Health will require storage and handling training for Primary and Back-up COVID-19 vaccine coordinators. The Chief Medical Officer/Chief Executive Officer (CMO/CEO) signatory and Primary and Back-up COVID-19 vaccine coordinators must ensure that staff onsite know correct procedures for maintaining vaccine cold chain. Primary and Back-up COVID-19 vaccine coordinators are responsible for ensuring correct COVID-19 vaccine management. Providers must be available and onsite with appropriate staff to receive vaccine shipments.

The facility ensures the COVID-19 Vaccine Provider Agreement has a correct physical address to receive vaccines, correct hours of operation with a four-hour window for each facility to receive vaccines, a primary point of contact and back-up for vaccine questions, appropriate and



adequate storage units to house vaccines and temperature monitoring devices that meet requirements for vaccine storage units.

Provider sites receiving vaccine have storage units that can store the vaccine being received. The type and capacity of refrigerator, freezer, and ultra-cold storage will be tracked in the enrollment profile record. Storage and handling temperature requirements for COVID-19 vaccine will vary:

- o Refrigerated: 2°C to 8°C
 - o Frozen: -15°C to -25°C
 - o Ultra-cold: -60°C to -80°C
 - o Ongoing stability testing may impact requirements (this information is based on COVID19 Vaccination Program Interim Playbook for Jurisdiction Operations).
- Vaccines that require ultra-cold storage can be stored in their shipping containers with dry ice. Prior to approving orders for vaccine with ultra-cold storage requirements, DC Health will ensure that there is a documented ultra-cold freezer or there is access to a dry ice vendor.

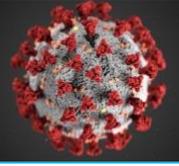
Providers must continuously monitor COVID-19 vaccine with a Temperature Monitoring Device (TMD), also known as a Digital Data Logger (DDL). Providers are required to submit DDL reports weekly, or with every order (whichever comes first) to COVID-19-vaccine@dc.gov if they are unable to digitally report this information in the immunization information system (IIS). All staff members who might receive vaccine deliveries must be aware of the importance of maintaining the cold chain.

COVID-19 Vaccine Provider staff must be properly trained in vaccine storage and handling – [You Call the Shots Module 10](#), Epidemiology and Prevention of Vaccine-Preventable Diseases (the [Pink Book](#)): [Storage and Handling Chapter, Vaccine Storage and Handling Guidelines and Recommended Resources](#) on vaccine storage and handling.

Providers who are currently enrolled in the VFC/VFA programs and are familiar with vaccine requirements for storage and handling, and administration should have available required vaccine storage and monitoring equipment; completed required annual training; have in place primary and secondary vaccine coordinators who will be responsible for vaccine monitoring and inventory and have in place a routine; and an emergency vaccine management plan. These requirements will also be expected.

New providers will be assessed for storage and handling capabilities and ability to meet and adhere to requirements by utilizing enrollment checklists. (Reference: CDC's Vaccine Storage & Handling Toolkit and Addendum).

Accurate vaccine inventory management is critical. The Centers for Disease Control and Prevention (CDC) centralized distributor, McKesson, will deliver vaccine directly to the provider site; for ultra-cold vaccines, the vaccines will be shipped directly from the manufacturer.



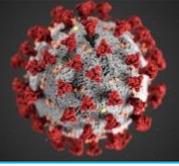
If there are any storage and handling incidents, vaccine must be marked as “Do not use” and quarantined to prevent accidental administration. The vaccine manufacturer will determine viability.

- Satellite, temporary, or off-site settings
Utilize “Checklist of Best Practices for Vaccination Clinics Held at Temporary, or Off-Site, Satellite Clinics”, located at <https://www.izsummitpartners.org/content/uploads/2019/02/off-site-vaccination-clinic-checklist.pdf>. This checklist is a step-by-step guide to help clinic coordinators/supervisors overseeing vaccination clinics held at satellite, temporary, or offsite locations follow CDC guidelines and best practices for vaccine shipment, transport, storage, handling, preparation, administration, and documentation.

DC Health will work with providers that are planning to host clinics to ensure that the quantity of vaccine received is based on population anticipated to be vaccinated. Provider sites that utilize satellite, temporary, or off-site settings must understand and use appropriate transport and storage protocol. Sites conducting clinics at satellite, temporary, or off-site settings must contact DC Health to ensure the transport protocol is followed, and to receive additional DDLs if needed. Storage units for COVID-19 vaccine products must be monitored continuously. At the end of clinic, vaccine must be moved back to a fixed storage unit with temperature monitoring.

- Planned redistribution
Planned redistribution from depots to individual locations and from larger to smaller locations may be allowed by approval from DC Health and only with the CDC COVID-19 Vaccine Redistribution Agreement completed. Immunization staff/designated transporter will transport vaccine for redistribution according to written protocols/checklist from depots to individual locations and from larger to smaller locations. Vaccine to be transported according to recommended guidelines set forth by CDC/Manufacturer. CDC has capacity for centralized distribution to most vaccination provider sites.
- Unplanned repositioning among provider locations
Monthly inventories by each provider site will be monitored accessing vaccine usage and vaccine inventory. If provider is unable to use, vaccine will be relocated to other provider site by DC Health staff.

B. *Describe how your jurisdiction will assess provider/redistribution depot COVID-19 vaccine storage and temperature monitoring capabilities.*



DC Health plans to purchase required storage equipment and temperature monitoring devices. Remote monitoring and alarm system will be set up to ensure prompt notification of temperature excursion. Routine/yearly maintenance contracts will be required, along with generators/back-up power supply in place in event of power outage. Providers will also be required to monitor/record temperature of storage devices twice daily. Temperature logs and digital data logs will be requested to be submitted to DC Health weekly and monthly. Protocols are currently in place for temperature excursions.

Section 9: COVID-19 Vaccine Administration Documentation and Reporting

DC Health is in the process of transitioning to a new Immunization Information System (IIS) for the District, through a contract with STCHealth. The goal is to have the core components of the new platform, STC|ONE, stood up to support onboarding of new providers (whose EHRs do not interface with the current IIS) and migration of data for existing providers, to support Phase 1 of vaccine distribution. The new IIS is tentatively planned for release and availability in early December 2020, based on finalization of Required Data Elements for Reporting and Related Specifications.

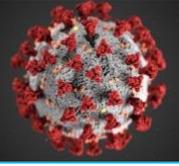
DC Health expects that the system will be fully implemented prior to Phase 2 of the vaccine distribution.

- A.** *Describe the system your jurisdiction will use to collect COVID-19 vaccine doses administered data from providers.*

DC's new IIS or DOCIIS 2.0 (District of Columbia Immunization Information System) will be able to capture all historical and administered vaccinations, including the new COVID-19 vaccine. STCHealth will provide a COVID-19 specific dashboard to give a visual representation of this data which will also have the functionality and ability to export the data for the purposes of reporting to DC Health and CDC daily. Providers will have access to DOCIIS 2.0 through their Organizational/Facility-level account access. Individual facility-level accounts will be created for vaccinators who do not have initial access. This will allow vaccinators to log each vaccine they administer. The current IIS or DOCIIS has the capability to record vaccines administered via electronic submission; and using a separate portal to capture paper submission, which require manual updates by staff.

- B.** *Describe how your jurisdiction will submit COVID-19 vaccine administration data via the Immunization (IZ) Gateway.*

As of October 2020, DC Health is connected to IZ Gateway. Initial access for setting up connections, have already been established. COVID-19 required vaccine information (standard and optional data elements if captured) will be collected via DOCIIS 2.0 and sent to CDC via the



IZ Gateway, using current HL7 standards. An alternative plan is to send a CSV file or similar file format directly to the CDC via established methods of secure transfer (SFTP site).

- C.** *Describe how your jurisdiction will ensure each COVID-19 vaccination provider is ready and able (e.g., staff is trained, internet connection and equipment are adequate) to report the required COVID-19 vaccine administration data elements to the IIS or other external system every 24 hours.*

DC Health will work with STCHealth to train Immunization Program staff and providers (via provider group training) on the use of system and reporting. COVID-19 vaccination providers will have access to training resources, which will be accessible on the DOCIIS 2.0 webpage. Training topics will include how to use MyIR, administer vaccines, create and print patient records, add and search for patients, and create reports. DOCIIS 2.0 Users will have significant support through a Provider Support Plan from STCHealth, which will include increased support for COVID-19, over a six-month period, to address high volume calls from IIS users. This includes support via a Help Desk Chat, email, and phone 24/7.

- D.** *Describe the steps your jurisdiction will take to ensure real-time documentation and reporting of COVID-19 vaccine administration data from satellite, temporary, or off-site clinic settings.*

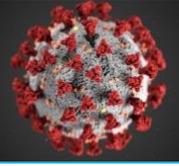
STC|ONE's MassImms Module can support real-time reporting from satellite, temporary, or off-site clinic settings. This module is used in conjunction with the dashboard. COVID-19 vaccine providers will be required to enter vaccine administration data into DOCIIS 2.0 within 12 hours of administration. If internet access is not available, providers are required to complete the Vaccine Administration Record (VAR) form during the vaccination event and record it in DOCIIS 2.0 within 12 hours.

- E.** *Describe how your jurisdiction will monitor provider-level data to ensure each dose of COVID-19 vaccine administered is fully documented and reported every 24 hours as well as steps to be taken when providers do not comply with documentation and reporting requirements.*

STC|ONE (VOMS 2) tracks vaccine wastage, which will also be displayed using the dashboard for visual display and for exporting to the CDC. Release of this in November will be dependent on final CDC data elements required for reporting and associated specs. DC Health will monitor provider-level data using the dashboard. The system will flag incomplete/inaccurate information. Providers will be contacted to correct errors.

- F.** *Describe how your jurisdiction will generate and use COVID-19 vaccination coverage reports.*

COVID-19 vaccination coverage reports will be generated in DOCIIS 2.0. These reports will be used to track and monitor COVID-19 vaccination rate and coverage across the District, as well as determine pockets of needs for additional targeting.



Section 10: COVID-19 Vaccination Second-Dose Reminders

- A.** *Describe all methods your jurisdiction will use to remind COVID-19 vaccine recipients of the need for a second dose, including planned redundancy of reminder methods.*

The new IIS will have a built in reminder/recall system (via e-mail, mail, and phone) that can support a second dose reminder. Another feature for future use is *MyIR* which includes a mobile tool that pushes out notifications and is tied to geocoded scheduling information. Currently, providers use their reminder/recall systems that is integrated with their Electronic Health Record. A paper reminder given to the patient at the time of first administration will also be used.

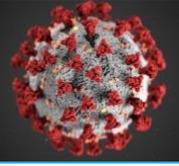
Section 11: COVID-19 Requirements for IISs or Other External Systems

- A.** *Describe your jurisdiction's solution for documenting vaccine administration in temporary or high-volume vaccination settings (e.g., CDC mobile app, IIS or module that interfaces with the IIS, or other jurisdiction-based solution). Include planned contingencies for network outages or other access issues.*

STC|ONE provides options for capturing vaccine information within the registry, via an electronic interface with EHRs, or via a MassImms Module. The registry application and MassImms Module can both be used in conjunction with mobile hot-spots to help ensure network connectivity. For providers with interface problems, manual entry is also an option. In the event of a network outage or in high-volume vaccination settings, COVID-19 vaccinators are required to complete a VAR during the vaccination event and record it in DOCIIS 2.0 within 12 hours.

- B.** *List the variables your jurisdiction's IIS or other system will be able to capture for persons who will receive COVID-19 vaccine, including but not limited to age, race/ethnicity, chronic medical conditions, occupation, membership in other critical population groups.*

DOCIIS 2.0 will be able to capture the following variables: administration location (facility name/ID, type), administration address, administration date, CVX (product), dose number, IIS recipient ID, IIS vaccination event ID, lot number (unit of use, unit of sale), MVX (manufacturer), recipient address, recipient date of birth, recipient name, recipient sex, recipient race, recipient ethnicity, sending organization, vaccine administering provider suffix, vaccine administering



site, vaccine expiration date, vaccine route of administration. STCHealth will accommodate any updated requirements within HL7 guidelines.

- C.** *Describe your jurisdiction's current capacity for data exchange, storage, and reporting as well as any planned improvements (including timelines) to accommodate the COVID-19 Vaccination Program.*

DOCIS 2.0 will have the functional capability to capture all patient vaccination data. This gives us the ability to track and monitor when patients receive vaccines, the number of doses received, and when and where they received it. DOCIS 2.0 will also have the capability to run coverage reports and manage vaccine inventory. STC|ONE will allow the option to exchange data through HL7 interfaces, the IZ Gateway, and dashboard visualization with incorporated reporting that meet CDC specified increments.

- D.** *Describe plans to rapidly enroll and onboard to the IIS those vaccination provider facilities and settings expected to serve healthcare personnel (e.g., paid and unpaid personnel working in healthcare settings, including vaccinators, pharmacy staff, and ancillary staff) and other essential workers.*

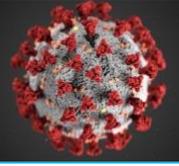
DC Health has already implemented its online pandemic provider enrollment, which includes the CDC COVID-19 Vaccination Program Provider Agreement. STCHealth has products and services available to assist providers to onboard rapidly by streamlining electronic provider registration and pandemic registration processes, managing onboarding provider interface connections, and ensuring data quality.

Once the form has been completed online, providers will email the signature sections of the agreement to COVID-19.vaccine@dc.gov. Staff will process completed agreements, then update DOCIS 2.0 to indicate the organization and facilities as COVID-19 providers. Finally, we will notify the facility to inform them of their selection as COVID-19 providers via email. As of November 22nd, 2020 there are over 85 provider groups and facilities enrolled.

- E.** *Describe planned backup solutions for offline use if internet connectivity is lost or not possible.*

COVID-19 vaccine providers will be required to enter vaccine administration data into DOCIS 2.0 (new IIS) within 12 hours of administration. If internet access is not available, providers are required to complete the Vaccine Administration Record (VAR) form during the vaccination event and record it in the IIS within 12 hours.

- F.** *Describe how your jurisdiction will monitor data quality and the steps to be taken to ensure data are available, complete, timely, valid, accurate, consistent, and unique.*



DC Health in coordination with STCHealth is responsible to ensure high data quality standards and complete and accurate data input through various data quality reports and system monitoring. Staff will monitor provider-level data by running daily immunization reports for each site. Functionalities also evaluates trends over time, trends by EHR type, message completeness and message consistency. Additionally, STC|ONE includes deduplication and advanced patient matching logic.

Section 12: COVID-19 Vaccination Program Communication

A. Describe your jurisdiction's COVID-19 vaccination communication plan, including key audiences, communication channels, and partner activation for each of the three phases of the COVID-19 Vaccination Program.

I. BACKGROUND

Starting before COVID-19 vaccines are available, clear, effective communication will be essential to implementing a successful COVID-19 Vaccination Program. Building vaccine confidence broadly and among groups anticipated to receive early vaccination, as well as dispelling vaccine misinformation, are critical to ensure vaccine uptake.

DC is identifying credible, trusted spokespersons to communities at risk through partnerships and stakeholder groups including those described above in our Health and Medical Coalition, Immunize DC Immunization Coalition and the Scientific Advisory Committee. Additionally, DC Health leadership routinely participate in community meetings. The content of DC's messaging is further described below, but messaging will targeted to District residents, many of whom will fall in a high-risk, highly disproportionately affected by COVID-19 community. Similar to influenza campaigns the District has presented to target residents age 65 and older, or women of child-bearing health to focus on maternal health, a similar campaign will be constructed to convey the importance of COVID-19 vaccine in these sub-populations.

DC Health also produced a poll to assess District resident's predispositions to the COVID-19 vaccine. Results confirmed the anticipation of less acceptance of the vaccine by communities of color, specifically those who are essential workers and healthcare workers (Figure 9)

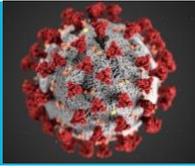
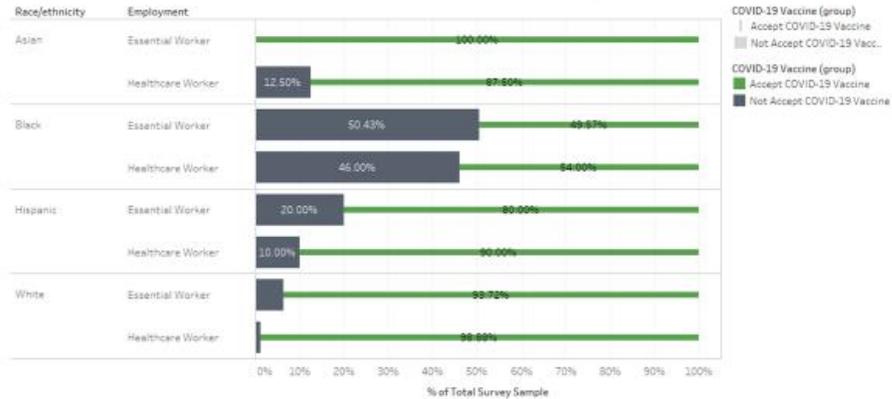


Figure 9.

COMMUNITY FEEDBACK STRATEGY

Race/ethnicity and employment status of sample who would accept getting COVID-19 vaccine



% of Total Count of Covid-19 Vaccine Survey.csv for each Employment broken down by Race/Ethnicity. Color shows details about COVID-19 Vaccine (group). Size shows details about COVID-19 Vaccine (group). The marks are labeled by % of Total Count of Covid-19 Vaccine Survey.csv. The data is filtered on COVID-19 Vaccine, which keeps Definitely Yes, Probably Yes, Probably NO and Definitely NO. The view is filtered on Race/Ethnicity and Employment. The Race/Ethnicity filter has multiple members selected. The Employment filter keeps Healthcare Worker and Essential Worker.



Data from this tool and others will form the foundation of the community feedback strategy. One of the outputs of the Scientific Advisory Committee is to develop public messaging in several forms, including a 1-page fact sheet for District residents to convey the safety and efficacy of a COVID-19 vaccine (Figure 10 and 11).

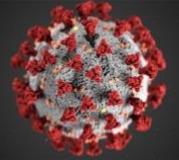
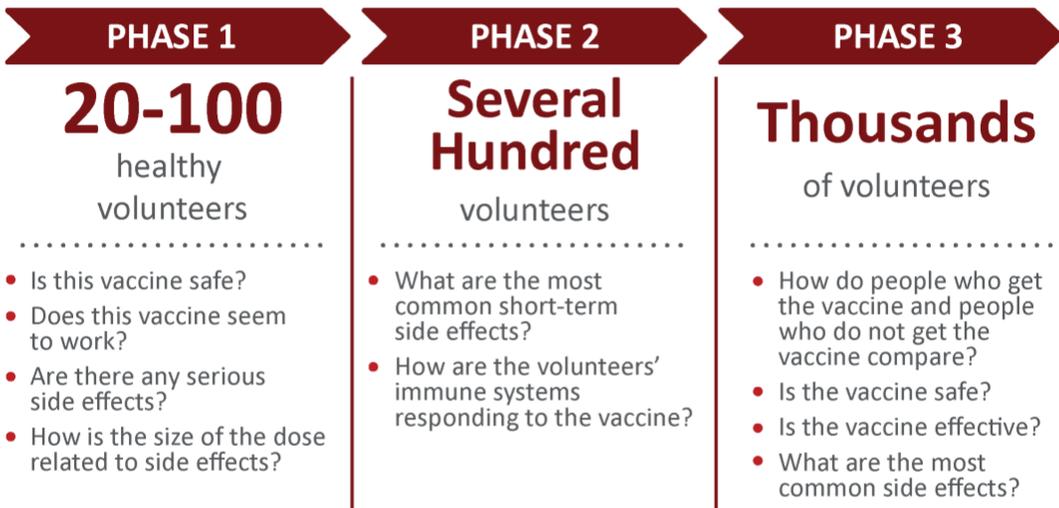


Figure 10.

How a New Vaccine is Developed, Approved and Manufactured

Before a new vaccine is ever given to people, **extensive lab testing** is completed in the pre-clinical phase. Once testing in people begins, the three phases of clinical trials are completed and the vaccine is then licensed.

The Food and Drug Administration (FDA), an independent, non-political agency, sets rules for the three phases of clinical trials to ensure the safety of the volunteers. These rules are set, not only for safety of volunteers, but to ensure safety and effectiveness of any vaccine.



FDA licenses the vaccine only if:

- ✓ It's safe
- ✓ It's effective

Vaccines are **made in batches** called lots.

The lots can only be released once FDA reviews their **safety and quality**.

The FDA inspects manufacturing facilities regularly to ensure **quality and safety**.

For more information, visit [fda.gov/cber](https://www.fda.gov/cber)

For more information on the District's COVID-19 response, visit [coronavirus.dc.gov](https://www.coronavirus.dc.gov)

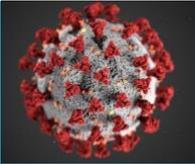


Figure 11.

How a Vaccine’s Safety Continues to Be Monitored

The Advisory Committee on Immunization Practices (ACIP) is an independent committee within the CDC made up of vaccine experts across the country. ACIP creates the U.S. Recommended Immunization Schedule. After a vaccine is added to the schedule, health experts continue to monitor the vaccine’s safety and effectiveness.

FDA and CDC closely monitor vaccine safety after the public begins using or receiving the vaccine.

Monitoring a vaccine after it is licensed helps ensure that possible side effects and risks associated with the vaccine are identified.

Vaccine Adverse Event Reporting System (VAERS)

VAERS collects and analyzes reports of adverse events that happen after vaccination. Anyone can submit a report, including parents, patients and healthcare professionals.



Vaccine Safety Datalink (VSD)

Post-Licensure Rapid Immunization Safety Monitoring (PRISM)



Scientists in the United States use two systems to actively monitor vaccine safety.

VSD can analyze healthcare information from over **24 million** people.

PRISM can analyze information from over **190 million** people.

Clinical Immunization Safety Assessment Project (CISA)

CISA is a collaboration between CDC and 7 medical research centers.

Vaccine safety experts assist U.S. healthcare providers with complex vaccine safety questions about their patients. CISA conducts clinical research studies to better understand vaccine safety and identify prevention strategies for adverse events following immunization.

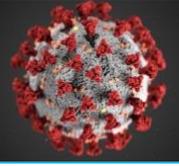


Vaccine recommendations are continually being monitored for safety and effectiveness through a multiple prong strategy.

For more information, visit cdc.gov/vaccinesafety

For more information on the District’s COVID-19 response, visit coronavirus.dc.gov





Frameworks such as Crises and Emergency Risk Communications (CERC), CDC’s Vaccinate with Confidence and the Stages of Change model will be infused in messaging to support vaccine hesitancy amongst the public. Additionally, the committee is developing tools and resources for the healthcare community to support clinical confidence.

All public messaging documents will be in plain language and translated into the official languages of the District. A vaccine page is under development on the District’s Coronavirus response page, coronavirus.dc.gov/vaccines.

A successful COVID-19 Vaccination Program will have lasting effects on the nation’s immunization system and overall vaccination efforts in the future. The District will use risk communication principles along with the CDC’s recently developed *Vaccinate with Confidence* framework, to develop messaging and guide overall COVID-19 vaccination communication strategies and tactics.

Immunization Program

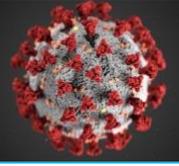
The Immunization Program, which is part of DC Health’s Community Health Administration helps reduce the spread of vaccine preventable diseases to residents, visitors, and those working or doing business in the District. This is accomplished through education, prevention, vaccine coverage monitoring, and engagement with healthcare providers. The mission of the DC Health Immunization Program is to reduce Vaccine Preventable Diseases (VPD) across the lifespan through vaccinations. The Immunization Program achieves its mission by focusing on five key areas: Vaccine Access (through the Vaccines For Children Program), Data Assessment and Management, Adult Immunization, Coalition Building, and Education and Training.

In support of the District’s response to COVID-19, DC Health is working with its partners to catch children up with routine vaccinations, inform strategies to address pockets of need, and expand public awareness on Vaccine Preventable Diseases (VPDs) and access points. This is a part of its multi-level, multi-sector, three-phased approach to educate and inform District residents about the COVID-19 vaccine and encourage vaccination.

The strategy will consist of a blend of past effective communication methods, with a focus on building capacity of key partners to support vaccination locations in each ward, and increasing collaboration with emergency preparedness partners. Media will be strategically placed in areas disproportionately impacted by COVID-19 based on DC Health data.

II. GOALS/OBJECTIVES

- Increase awareness of Vaccine Preventable Diseases
- Educate residents about the COVID-19 vaccine to change audience perception and easing skepticism
 - Development, authorization, distribution, and execution of COVID-19 vaccines and that situations are continually evolving.



- Ensure public confidence in the approval or authorization process, safety, and efficacy of COVID-19 vaccines.
- Help the public to understand key differences in FDA emergency use authorization and FDA approval (i.e., licensure).
- Communicate public health and vaccine safety messages to district residents and stakeholders to achieve 100% transparency
- Reach at least 80% of the identified target audiences through marketing and community outreach efforts

III. AUDIENCE(S)

- District residents, general public
- Employers, employees (living inside and outside of the District)
- Health/healthcare partners
- Facilities not connected to a system, not centralized

IV. MESSAGES

Draft messaging for each audience outlined in section III highlighting:

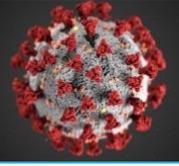
- Each vaccine distribution phase
- Vaccine availability
- Insurance coverage
- Importance of vaccines
- Preventive measures

All messages will be translated in the District's official languages

V. TACTICS/ACTIVITIES

- Media (traditional and digital)
 - Newspaper (large, small and language appropriate circulations) and digital ads
 - Radio & TV ads
 - Social Media
 - District Agency websites
 - Geotargeting
 - Bus ads
- Webinars and health notices
- Language based messaging and creative toolkit(s)
- Partner dissemination channels – newsletters/listservs, social media channels, networks
- Leverage CDC and/or NPHIC resources and creative and adapt for District target audiences
- Webinars

VI. EVALUATION

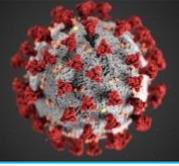


- Track and monitor public receptiveness to COVID-19 vaccination messaging.

Additional points to consider:

- DC continues to leverage its flu campaign to spread messaging (using numerous platforms) integrated with information on COVID-19. Partners representing/supporting critical populations will be asked to disseminate materials through their respective networks and touch points within the community.
- DC Health will use or modify CDC developed communication resources for key audiences, where appropriate. These resources will be available on the District's public-facing COVID-19 website.
- DC Health will work with District agencies to ensure messaging is uniformed, timely, and accurate.
- Communication and educational materials about COVID-19 vaccination provider enrollment, COVID-19 vaccine ordering, COVID-19 vaccine storage, handling, administration (i.e., reconstitution, adjuvant use, administration techniques), will be available in a variety of formats.
- A screening tool on the CDC website will help individuals determine their own eligibility for COVID-19 vaccine and direct them to [vaccine.finder.org](https://www.cdc.gov/vaccines/imz/downloads/#vaccinefinder).

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Section 13: Regulatory Considerations for COVID-19 Vaccination

- A. *Describe how your jurisdiction will ensure enrolled COVID-19 vaccination providers are aware of, know where to locate, and understand the information in any Emergency Use Authorization (EUA) fact sheets for providers and vaccine recipients or vaccine information statements (VISs), as applicable.*

Confirm authorization to administer vaccines.

Under District law, licensed physicians, nurses, pharmacists, and physician assistants are authorized to administer vaccines. The Department of Health will confirm that any additional providers administering vaccines are properly authorized. For example, under the current emergency authorizations, certain Paramedics can administer vaccines, but must first be certified to have an enlarged scope of practice. Once the emergency declaration ends, this authority would also cease. Licensure and certification is governed by District of Columbia law and regulation.

The District of Columbia will adhere to any federal law or regulation pertaining to liability protections.

There would also be a potential question as to liability in administering this new vaccine. As a medical countermeasure (MCM) provided through the Medical Countermeasures Distribution and Dispensing (MCMDD) program, as part of the Division of Strategic National Stockpile (DSNS) there would be liability protections for providers under the Public Readiness and Emergency Preparedness Act (PREP Act) or other laws pertaining to this plan. There may also be some specific liability provisions in the Emergency Use Authorization (EUA).

Available methods of communication:

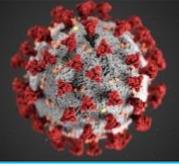
- Phone (HAN),
- Text,
- Email,
- Physical mail,
- WebEx.

Resources to ensure communication is received and understood – (contingent upon DC Health resources):

- Phone prompt survey
- Text w/ survey
- Email w/ survey
- Mail (Physical) reply
- WebEx live exam

Considerations:

- Tracking for potential audit (QA)
- Turnaround time
- Effort involved (ROI)



- Legal threshold met?
- B.** *Describe how your jurisdiction will instruct enrolled COVID-19 vaccination providers to provide Emergency Use Authorization (EUA) fact sheets or vaccine information statements (VISs), as applicable, to each vaccine recipient prior to vaccine administration.*
- Providers shall provide a VIS to all prospective patients during pre-vaccination intake.
 - Minors – provide VIS to parent or guardian.
 - VIS shall be in writing and be made available in multiple languages to accommodate language barriers
 - A POS signature shall be captured from vaccine recipients upon receipt of the VIS to validate delivery,
 - How can we assess understanding for VIS delivery?
- Considerations:
- What is (if applicable) the legal threshold versus best practices for ensuring understanding here?

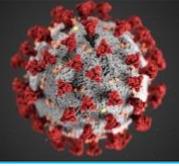
Section 14: COVID-19 Vaccine Safety Monitoring

- A.** *Describe how your jurisdiction will ensure enrolled COVID-19 vaccination providers understand the requirement and process for reporting adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS).*

Reporting of vaccine adverse events including vaccine administration errors will be included as part of the Cooperative Vaccine Agreement during enrollment. This includes monthly reminders to Providers. Information related to VAERS will be provided during provider/staff training. Reporting of adverse events via online or writable PDF form. <https://vaers.hhs.gov/>. Report may also be submitted to the DC Reporting and Surveillance Center (DCRC) online reporting system located at <https://dchealth.dc.gov/service/infectious-diseases>.

VAERS serves as an early warning system to detect possible safety problems in U.S. licensed vaccines. Accurate, complete, and timely reporting of post-vaccination health issues provides:

- Important information for vaccine safety monitoring and research;
- Educational/communication materials for VAERS:
<https://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafe-vaers-color-office.pdf>;
- Information for Healthcare Providers: <https://vaers.hhs.gov/>; and
- VAERS Fact Sheet for Healthcare Providers & General Public:
https://www.cdc.gov/vaccinesafety/pdf/VAERS_FactSheet1.pdf.



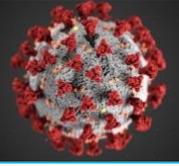
Section 15: COVID-19 Vaccination Program Monitoring

A. Describe your jurisdiction's methods and procedures for monitoring progress in COVID-19 Vaccination Program implementation:

DC Health will employ continuous monitoring pre-implementation, during implementation, and post full implementation of the COVID-19 Vaccination Plan. DC Health will use a three-pronged approach to its internal monitoring and reporting process that will individually assess core functions of the vaccination plan; progress towards completion of each plan component; and data indicators through ongoing COVID-19 surveillance, and vaccination coverage, using the District's IIS. Information will be compiled from local and national data sources to compare progress over time and in comparison to regional and national efforts.

Three-Pronged Approach:

1. Assessment of Core Functions – will be completed using an evaluation tool similar to the National Inventory of Core Capabilities for Pandemic Influenza Preparedness and Response. Core Functions Include:
 - Administrative Functions – budget, staffing, and supplies
 - Communications – media, dissemination, public response
 - Data Quality for IIS and other IT systems – availability, validity, timeliness, accuracy, completeness
 - Vaccine Distribution – process in place, process delineates between Phase 1 and Phase II distribution, allocations by provider or health system
 - Vaccine Ordering and Inventory – Sufficient vaccine has been ordered, all eligible (for Phase 2) providers have ordered vaccine, vaccine has been received
2. Vaccine Plan Metrics – the following metrics (and sample questions will be used):
 - Planning Committee
 - Has the planning committee been established?
 - Provider Enrollment
 - Does the committee/work group include collaboration with organizations serving critical population groups?
 - Dose Allocation
 - Is there a process for allocating initial vaccine doses?
 - Critical Populations
 - Has an estimated jurisdiction-level population size for persons belonging to the following groups been established?
 - Critical Workforce in healthcare services
 - Long-term Care Facility Residents
 - People 65 years of age or older
 - Persons with underlying medical conditions
 - People from racial and ethnic minority groups



- People experiencing homelessness/living in shelters
- Second Dose Reminders
 - Is the second dose reminder process fully functional?
 - Do providers have a second dose reminder plan in place?
- 3. Disease Surveillance and Vaccination Coverage (quantified data)
 - Disease Surveillance – # of cases to date, # of lives loss, disease burden, influenza cases (by age groups)
 - Vaccination Coverage – demographics, # of persons vaccinating (i.e. # of completed doses, doses completed on time), # of persons vaccinated representing specific priority groups

Weekly Planning Team meetings will be used to demonstrate progress of the plan metrics and will be reported using CDC for reporting to their dashboards (weekly flu and COVID-19 response) and DC Health designed dashboard that address key plan indicators. The District's IIS will support data analytics for vaccine coverage, vaccine ordering and distribution. Information will be sent to CDC through VAMS for Phase I and then directly to IZ Gateway for Phase 2.

B. Describe your jurisdiction's methods and procedures for monitoring resources, including:

- *Budget* – Use of accounting system to track expenditures using specific Index assigned for the COVID-19 Vaccine Plan.
- *Staffing* – collaboration with the District's Department of Human Resources and DC Health HR Department to address turnover and to assist with expediting onboarding of staff.
- *Supplies* – Work with CFO's Office to ensure a procurement process is in place for ordering and distribution of ancillary supplies.

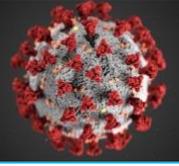
Tasks for Budget, Staffing, and Supplies will flow through the *District Response Organization Structure*.

C. Describe your jurisdiction's methods and procedures for monitoring communication, including:

- *Message delivery*
- *Reception of communication messages and materials among target audiences throughout jurisdiction*

DC will develop monitoring processes appropriate for each type of media channel utilized.

- Social media messaging
 - Twitter - # of likes, retweets, mentions
- Geofencing
 - The # of impressions, # of clicks
- Dissemination through partners
 - How many persons reached?



- D.** *Describe the COVID-19 Vaccination Program metrics (e.g., vaccination provider enrollment, doses distributed, doses administered, and vaccination coverage), if any that will be posted on your jurisdiction’s public-facing website, including the exact web location of placement.*

COVID-19 surveillance data is posted on coronavirus.dc.gov webpage. Plan metrics will be reported and discussed internally and relevant updates made available to the public and media sources, on a weekly basis.

As required, DC will report CDC-defined data elements related to vaccine administration daily (i.e., every 24 hours). CDC will provide information on these data elements to jurisdictions

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Appendix A.

Recommendations for Initial COVID-19 Vaccine Prioritization

As of the end of November 2020, the COVID-19 pandemic has claimed over 260,000 lives in the United States and over 670 lives in the District of Columbia. Currently two promising vaccine candidates are nearing U.S. Food and Drug Administration (FDA) Emergency Use Authorization, with others to likely come in months ahead. So long as the demand for the vaccine exceeds the supply, the U.S. federal government will determine State and Jurisdiction allocations of vaccine and cadence of vaccine delivery. The District of Columbia will then approve allocations and orders for vaccine providers as well as provide recommendations for population prioritization.

The District will follow the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) recommendations for vaccination. Additionally, the District will follow the “phased” priority approach outlined by the CDC. Per the CDC, Phase 1-A includes “Paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials and are unable to work from home”. Phase 1-B includes “other essential workers and people at higher risk of severe COVID-19 illness”.

D.C. Department of Health (DC Health) estimates that over 85,000 individuals who work in the District meet Phase 1-A criteria, including those in inpatient and outpatient settings, ancillary care settings, long-term care settings, intermediate care and assisted living settings, home health aides, Fire and Emergency Medical Services, and front-line public health workers.

Initial vaccine allotments from the federal government to the District will be limited, and it may take months to vaccinate the Phase 1 population. To determine a framework to prioritize within the Phase 1-A population, DC Health:

- Reviewed CDC’s “The Advisory Committee on Immunization Practices’ Ethical Principles for Allocating Initial Supplies of COVID-19 Vaccine – United States, 2020” Morbidity and Mortality Weekly Report
- Reviewed the National Academies of Sciences, Engineering, & Medicine’s “A Framework for Equitable Allocation of Vaccine for the Novel Coronavirus”
- Sought guidance from Daniel Sulmasy MD, PhD - Andre’ Hellegers Professor of Biomedical Ethics and Acting Director of the Kennedy Institute of Ethics at Georgetown University
- Engaged DC Health’s Scientific Advisory Committee for the Development and Implementation of a Safe, Effective, and Equitable COVID-19 Vaccine Distribution Program in the District of Columbia

The guiding ethical principles to this prioritization include beneficence, concern for the common good, justice, respect for persons, mitigate health inequities, and promote transparency. Additionally, DC Health concurs with CDC ACIP’s view on prioritization: “ACIP viewed the following characteristics as critical for its ethical approach to COVID-19 vaccine allocation when supply is limited: simplicity in structure and definitions, acceptability to stakeholders, and ease of application, both at the national and state, tribal local, and territorial levels”.

On a practical level, it is important to note that the Pfizer/BioNTech vaccine requires ultra-cold storage (-70 degrees Celsius) and has complex vaccine handling requirements. In the District, larger acute care hospitals have the storage capacity for this product. However, the Moderna/NIH vaccine does not require ultra-cold storage and has simpler vaccine handling requirements. The District will not mandate any individual or group of individuals receive a COVID-19 vaccine at this time.

District considerations for initial vaccine allocation to healthcare facilities

1. Ability to safely store and administer the vaccine as well as report results to DC Health and CDC
2. Burden of COVID-19 cases historically throughout the pandemic
3. Ability to efficiently and effectively administer the vaccine soon after vaccine delivery
4. Capacity to partner and coordinate with other entities and high-priority populations
5. Ability to provide vaccine education and counseling as well as coordination for wrap around medical and social services
6. Means to ensure minimal to no waste of vaccine

Healthcare facility recommendations for initial vaccine allocation

Healthcare institutions and providers should prioritize those individuals who work in front-line settings where they have direct exposure to symptomatic patients with potential COVID-19.

A higher priority should be directed to those settings in which healthcare workers may not know patients' SARS-CoV-2 status prior to interaction. This higher priority can be identified as emergency or emergency-like settings inclusive of Emergency Departments, Labor and Delivery Units, Urgent Care settings, and Pre-Hospital Emergency services. Healthcare institutions and providers should prioritize all individuals equally in each setting (inclusive of providers, nurses, health technicians, ancillary staff, and environmental services). The next priority group should be directed to those settings in which healthcare workers are increasingly likely to encounter and have direct exposure to a high number of COVID-19 patients. These settings can include Intensive Care Units, Respiratory Care Units, and certain COVID-19 specific care units, for example.

Attachments:

1. "The Advisory Committee on Immunization Practices' Ethical Principles for Allocating Initial Supplies of COVID-19 Vaccine – United States, 2020" Morbidity and Mortality Weekly Report
2. National Academies of Sciences, Engineering, & Medicine's "A Framework for Equitable Allocation of Vaccine for the Novel Coronavirus"
3. Correspondence from Daniel Sulmasy MD, PhD - Andre' Hellegers Professor of Biomedical Ethics and Acting Director of the Kennedy Institute of Ethics at Georgetown University

The Advisory Committee on Immunization Practices' Ethical Principles for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020

Nancy McClung, PhD¹; Mary Chamberland, MD^{1,2}; Kathy Kinlaw, MDiv³; Dayna Bowen Matthew, JD, PhD⁴; Megan Wallace, DrPH^{1,5}; Beth P. Bell, MD⁶; Grace M. Lee, MD⁷; H. Keipp Talbot, MD⁸; José R. Romero, MD⁹; Sara E. Oliver, MD¹; Kathleen Dooling, MD¹

To reduce the spread of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19) and its associated impacts on health and society, COVID-19 vaccines are essential. The U.S. government is working to produce and deliver safe and effective COVID-19 vaccines for the entire U.S. population. The Advisory Committee on Immunization Practices (ACIP)* has broadly outlined its approach for developing recommendations for the use of each COVID-19 vaccine authorized or approved by the Food and Drug Administration (FDA) for Emergency Use Authorization or licensure (1). ACIP's recommendation process includes an explicit and transparent evidence-based method for assessing a vaccine's safety and efficacy as well as consideration of other factors, including implementation (2). Because the initial supply of vaccine will likely be limited, ACIP will also recommend which groups should receive the earliest allocations of vaccine. The ACIP COVID-19 Vaccines Work Group and consultants with expertise in ethics and health equity considered external expert committee reports and published literature and deliberated the ethical issues associated with COVID-19 vaccine allocation decisions. The purpose of this report is to describe the four ethical principles that will assist ACIP in formulating recommendations for the allocation of COVID-19 vaccine while supply is limited, in addition to scientific data and implementation feasibility: 1) maximize benefits and minimize

harms; 2) promote justice; 3) mitigate health inequities; and 4) promote transparency. These principles can also aid state, tribal, local, and territorial public health authorities as they develop vaccine implementation strategies within their own communities based on ACIP recommendations.

The ACIP COVID-19 Vaccines Work Group has met several times per month (approximately 25 meetings) since its establishment in April 2020. Work Group discussions included review of the epidemiology of COVID-19 and consultation with experts in ethics and health equity to inform the development of an ethically principled decision-making process. The Work Group reviewed the relevant literature, including frameworks for pandemic influenza planning and COVID-19 vaccine allocation (3–8); summarized this information; and presented it to ACIP. ACIP supported four fundamental ethical principles to guide COVID-19 vaccine allocation decisions in the setting of a constrained supply. Essential questions that derive from these principles can assist in vaccine allocation planning (Table 1).

Maximize benefits and minimize harms. Allocation of COVID-19 vaccine should maximize the benefits of vaccination to both individual recipients and the population overall. These benefits include the reduction of SARS-CoV-2 infections and COVID-19–associated morbidity and mortality, which in turn reduces the burden on strained health care capacity and facilities; preservation of services essential to the COVID-19 response; and maintenance of overall societal functioning. Identification of groups whose receipt of the vaccine would lead to the greatest benefit should be based on scientific evidence, accounting for those at highest risk for SARS-CoV-2 infection or severe COVID-19–related disease or death, and the essential role of certain workers. The ability of essential workers, including health care workers and non–health care

*The ACIP includes 15 voting members responsible for making vaccine recommendations. Fourteen of the members have expertise in vaccinology, immunology, pediatrics, internal medicine, nursing, family medicine, virology, public health, infectious diseases, and/or preventive medicine; one member is a consumer representative who provides perspectives on the social and community aspects of vaccination. In addition to the 15 voting members, ACIP includes eight ex officio members who represent other federal agencies with responsibility for immunization programs in the United States, and 30 nonvoting representatives of liaison organizations that bring related immunization expertise. <https://www.cdc.gov/vaccines/acip/members/index.html>.



TABLE 1. Essential questions for COVID-19 vaccine allocation planning related to ethical principles — United States, 2020

Ethical principle	Essential question
Maximize benefits and minimize harms	What groups are at highest risk for SARS-CoV-2 infection, COVID-19 disease, hospitalization, and death?
	What groups are essential to the COVID-19 response?
	What groups are essential to maintaining critical functions of society?
	What are the important characteristics of these groups (e.g., size or geographic distribution) that might inform the magnitude of benefit based on the amount of vaccine available or its characteristics?
Promote justice	Does the allocation plan result in fair and equitable access of the vaccine for all groups?
	How do characteristics of the vaccine and logistical considerations affect fair access for all persons?
	Does allocation planning include input from groups who are disproportionately affected by COVID-19 or face health inequities resulting from social determinants of health, such as income and health care access?
Mitigate health inequities	Does the plan identify and address barriers to vaccination among any groups who are disproportionately affected by COVID-19 or who face health inequities resulting from social determinants of health, such as income and health care access?
	Does the allocation plan contribute to a reduction in health disparities in COVID-19 disease and death?
	What health inequities might inadvertently result from the allocation plan, and what interventions could remove or reduce them?
	Is there a mechanism for timely assessment of vaccination coverage among groups experiencing disadvantage and the possibility for course correction if inequities are identified?
Promote transparency	How does development of the allocation plan include diverse input, and if possible, public engagement?
	Are the allocation plan and evidence-based methods publicly available?
	Is the allocation plan clear about what is known and unknown and about the quality of available evidence?
	What is the process for revision of allocation plans based on new information?
	Is there a mechanism to report demographic data elements for vaccine recipients (e.g., age, race/ethnicity, and occupation) to support equitable vaccination coverage?

Abbreviation: COVID-19 = coronavirus disease 2019.

workers, to remain healthy has a multiplier effect (i.e., their ability to remain healthy helps to protect the health of others or to minimize societal and economic disruption). Some of these workers are at increased risk for SARS-CoV-2 infection because of their limited ability to maintain physical distance in the workplace or because they do not have consistent access to recommended personal protective equipment.

Promote justice. Inherent in the principle of justice is an obligation to protect and advance equal opportunity for all persons to enjoy the maximal health and well-being possible. Justice rests on the belief in the fundamental value and dignity of all persons. Allocation of COVID-19 vaccine should promote justice by intentionally ensuring that all persons have equal opportunity to be vaccinated, both within the groups recommended for initial vaccination, and as vaccine becomes more widely available. This includes a commitment to removing unfair, unjust, and avoidable barriers to vaccination that disproportionately affect groups that have been economically or socially marginalized, as well as a fair and consistent implementation process. Input from a range of external entities, partners, and community representatives is particularly important in developing and assessing allocation plans.

Mitigate health inequities. Health equity is achieved when every person has the opportunity to attain his or her full health potential and no one is disadvantaged from achieving this potential because of social position or other socially determined circumstances.[†] Disparities in the severity of COVID-19 and COVID-19–related death, as well as inequities in social determinants of health that are linked to COVID-19 risk, such as income or health care access and utilization, are well documented among certain racial and ethnic minority groups (9). Vaccine allocation strategies should aim to both reduce existing disparities and to not create new disparities. Efforts should be made to identify and remove obstacles and barriers to receiving COVID-19 vaccine, including limited access to health care or residence in rural, hard-to-reach areas.

Promote transparency. Transparency relates to the decision-making process and is essential to building and maintaining public trust during vaccine program planning and implementation. The underlying principles, decision-making processes, and plans for COVID-19 vaccine allocation must be evidence-based, clear, understandable, and publicly available. To the extent possible, considering the urgency of the COVID-19

[†] <https://www.cdc.gov/chronicdisease/healthequity/index.htm>.

response, public participation in the creation and review of the decision-making process should be facilitated. In addition, when feasible, tracking administration of vaccine to the groups recommended for initial vaccine allocation can contribute to transparency and trust in the process. In an ongoing public health response, the situation continually evolves as new information becomes available. Transparency includes being clear about the level of certainty in the available evidence and communicating new information that might change recommendations in a timely fashion.

For the period when the supply of COVID-19 vaccine will be limited, ACIP has considered four groups for initial vaccine allocation. These include health care personnel, other essential workers, adults with high-risk medical conditions, and adults aged ≥ 65 years (including residents of long-term care facilities) (Table 2). These groups were selected based on available scientific data, vaccine implementation considerations, and ethical principles. The principle of transparency is applied across the entirety of the vaccine allocation decision-making process. ACIP's meetings are open to the public, meeting minutes and archived webcasts are available online, and data (including data from vaccine clinical trials) and analytic methods used in developing ACIP recommendations are publicly available.[§] Members of the public are invited to submit written comments to the Federal Register or provide oral comment during ACIP meetings. ACIP's 30 nonvoting representatives from liaison organizations facilitate engagement with professional medical and public health organizations and other stakeholders and partners.

All four groups proposed for initial allocation of COVID-19 vaccine merit strong consideration from an ethical perspective. Current planning scenarios estimate, however, that the expected number of doses during the first weeks of vaccine distribution might only be sufficient to vaccinate approximately 20 million persons.[¶] Although there is considerable overlap between groups^{**} (10), the initial supply will not be adequate to vaccinate the entirety of all four groups; for example, there are approximately 100 million health care personnel and essential workers (Table 2). Published frameworks for COVID-19 allocation and ACIP discussions indicate a clear consensus that the first allocation of COVID-19 vaccine supplies should be directed to health care personnel (1,5–8); discussion of allocation to the other three groups is ongoing. As additional vaccine supplies become available, other groups may be vaccinated concurrent with health care personnel.

[§] <https://www.cdc.gov/vaccines/acip/index.html>.

[¶] https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.

^{**} There is overlap among these four groups. For example, in one analysis, among the 3.8% of U.S. adults who work directly with patients as health care workers, 38.6% have high-risk medical conditions or are aged >65 years.

Discussion

During a pandemic, ethical guidelines can help steer and support decisions around prioritization of limited resources (3,4). Consideration of ethical values and principles has featured prominently in discussions about allocation of COVID-19 vaccines. This consideration is particularly relevant because the COVID-19 pandemic has highlighted long-standing, systemic health and social inequities. Although various frameworks for COVID-19 vaccine allocation demonstrate differences in their structure (e.g., based on varying combinations of different goals, objectives, criteria, and other structural elements) and emphasis (e.g., inclusion of global and national considerations), nearly all reference values and principles similar to those which ACIP considers fundamental (5–8). ACIP viewed the following characteristics as critical for its ethical approach to COVID-19 vaccine allocation when supply is limited: simplicity in structure and definitions; acceptability to stakeholders; and ease of application, both at the national and state, tribal, local, and territorial levels.

Allocation of limited vaccine supplies is complicated by efforts to address the multiple goals of a vaccine program, most notably those related to the reduction of morbidity and mortality and the minimization of disruption to society and the economy. If the goals of a pandemic vaccination program are not clearly articulated and prioritized, drawing distinctions between groups that merit consideration for allocation of vaccine when supply is constrained can become difficult. The unanimity in opinion for early vaccination of health care personnel indicates that maintenance of health care capacity has emerged as a high priority in the context of a severe pandemic. This perspective aligns with ethical considerations for pandemic influenza planning (3,4). If vaccine supply remains constrained, it might be necessary to identify subsets of other groups for subsequent early allocation of COVID-19 vaccine. At the national, state, tribal, local, and territorial levels, such decisions should be guided, in part, by ethical principles and consideration of essential questions, with particular consideration of mitigation of health inequities in persons experiencing disproportionate COVID-19 morbidity and mortality. In the setting of a constrained supply, the benefits of vaccination will be delayed for some persons; however, as supply increases, there will eventually be enough vaccine for everyone.

In addition to ethical considerations, ACIP's recommendations regarding receipt of the initial allocations of COVID-19 vaccine during the period of constrained supply will be based on science (e.g., available information about the vaccine's characteristics such as safety and efficacy in older adults and epidemiologic risk) and feasibility of implementation (e.g., storage and handling requirements). Thus, ACIP's allocation recommendations will

TABLE 2. Application of ethical principles to four candidate groups for initial COVID-19 vaccine allocation — United States, 2020

Principles (with transparency across the decision-making process)	Candidate groups* (approximate no.)			
	Health care personnel [†] (21 million)	Other essential workers [†] (87 million)	Adults with high-risk medical conditions [§] (>100 million)	Adults aged ≥65 years (53 million)
Maximize benefits and minimize harms	Preserves health care services essential to the COVID-19 response and the overall health care system Multiplier effect [¶]	Preserves services essential to the COVID-19 response and overall functioning of society Multiplier effect [¶]	Reduces morbidity and mortality in persons with high incidence of COVID-19 disease and death ^{**}	Reduces morbidity and mortality in persons with high incidence of COVID-19 disease and death ^{††}
Promote justice	Addresses elevated occupational risk for SARS-CoV-2 exposure for those unable to work from home Promotes access to vaccine across a spectrum of HCP job types and settings	Addresses elevated occupational risk for SARS-CoV-2 exposure for those unable to work from home Promotes access to vaccine and reduces barriers to vaccination in occupations with low vaccine uptake ^{§§}	Will require focused outreach to vaccinate persons in this group who have no or limited access to health care or experience inequities in social determinants of health	Will require focused outreach to vaccinate persons in this group who have no or limited access to health care or experience inequities in social determinants of health
Mitigate health inequities	Racial and ethnic minority groups are disproportionately represented in low-wage HCP ^{¶¶}	Racial and ethnic minority groups are disproportionately represented in many essential industries ^{***} Approximately one quarter of essential workers live in low-income families ^{†††}	Increased prevalence of obesity and diabetes (most prevalent conditions in this group) among some racial and ethnic minority groups; increased prevalence of some medical conditions for persons in rural areas ^{§§§} Could increase health inequities because diagnosis of high-risk medical conditions requires access to health care	Although racial and ethnic minority groups are underrepresented among adults aged ≥65 years, certain groups have disproportionate COVID-19–related hospitalization and death rates ^{¶¶¶} Strict age-based criterion could increase disparities due to racial and social inequities, such as occupation, income, access to health care

Abbreviations: COVID-19 = coronavirus disease 2019; HCP = health care personnel.

* Health care personnel: paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials; other essential workers: person who conduct operations vital for continuing critical infrastructure, such as food, agriculture, transportation, education, and law enforcement; adults with high risk medical conditions: adults who have one or more high-risk medical conditions, such as obesity, diabetes, and cardiovascular disease; adults aged ≥65 years: includes adults living at home and approximately 3 million living in long-term care facilities. There is considerable overlap between groups, for example, many adults aged ≥65 years also have high-risk medical conditions.

[†] Essential workers during the COVID-19 response have been defined by the U.S. Department of Homeland Security Cybersecurity and Infrastructure Security Agency. https://www.cisa.gov/sites/default/files/publications/Version_4.0_CISA_Guidance_on_Essential_Critical_Infrastructure_Workers_FINAL%20AUG%2018v2_0.pdf.

[§] Medical conditions considered high-risk are updated routinely based on the best available scientific data: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>.

[¶] The ability of one or more groups to remain healthy helps protect the health of others and/or minimize disruption to society and the economy.

^{**} As of October 31, 2020, nearly 90% of persons with COVID-19–associated hospitalizations have at least one high-risk condition. Data are routinely updated through COVID-19–Associated Hospitalization Surveillance Network (COVID-NET) (https://gis.cdc.gov/grasp/COVIDNet/COVID19_5.html); in-hospital deaths reported to COVID-NET during March–May, 2020 were associated with certain underlying medical conditions (<https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1012/5872581>).

^{††} As of November 12, 2020, 80% of COVID-19 deaths were among adults aged ≥65 years. Data are routinely updated through CDC case-based surveillance (<https://covid.cdc.gov/covid-data-tracker/#demographics>); long-term care residents account for a large proportion of deaths among adults aged ≥65 years (<https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg/>).

^{§§} Influenza vaccination coverage is low among many non–health care essential workers; such coverage is lowest among construction workers (10.7%) (<https://www.cdc.gov/niosh/docs/2012-161/pdfs/2012-161.pdf?id=10.26616/NIOSH-PUB2012161>).

^{¶¶} Health Resources and Services Administration estimates from American Community Survey 2011–2015 (<https://bhw.hrsa.gov/sites/default/files/bhw/nchwa/diversityushealthoccupationstechnical.pdf>).

^{***} Among 742 food and agriculture workplaces in 30 states, 73% of workers were Hispanic or Latino and 83% of COVID-19 cases occurred in racial or ethnic minority workers (https://wwwnc.cdc.gov/eid/article/27/1/20-3821_article).

^{†††} Center for Economic and Policy Research estimates from American Community Survey, 2014–2018 (<https://cepr.net/a-basic-demographic-profile-of-workers-in-frontline-industries>).

^{§§§} National Center for Health Statistics. National Health Interview Survey, 2018. Estimates not available for Hawaiian/other Pacific Islander persons or for chronic kidney disease among American Indian/Alaska Native persons (<https://www.cdc.gov/nchs/nhis/ADULTS/www/index.htm>; <https://www.cdc.gov/mmwr/volumes/69/wr/mm6929a1.htm>).

^{¶¶¶} As of October 31, 2020, compared with COVID-19 hospitalization rates for adults aged ≥65 years who are non-Hispanic White, such rates were higher among adults aged ≥65 years who were non-Hispanic Black (rate ratio [RR] = 3.3), Hispanic or Latino (RR = 2.6), and non-Hispanic American Indian or Alaska Native (RR = 2.4). Data are routinely updated through COVID-NET (<https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>); adults aged ≥65 years who are Hispanic or non-Hispanic Black experience disproportionate COVID-19–associated death rates (https://www.cdc.gov/nchs/nvss/vsr/covid19/health_disparities.htm).

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Summary

What is already known about this topic?

During the period when the U.S. supply of COVID-19 vaccines is limited, the Advisory Committee on Immunization Practices (ACIP) will make vaccine allocation recommendations.

What is added by this report?

In addition to scientific data and implementation feasibility, four ethical principles will assist ACIP in formulating recommendations for the initial allocation of COVID-19 vaccine: 1) maximizing benefits and minimizing harms; 2) promoting justice; 3) mitigating health inequities; and 4) promoting transparency.

What are the implications for public health practice?

Ethical principles will aid ACIP in making vaccine allocation recommendations and state, tribal, local, and territorial public health authorities in developing vaccine implementation strategies based on ACIP's recommendations.

be made in conjunction with specific recommendations for the use of each FDA-authorized or licensed COVID-19 vaccine. Although the ethical principles in this report are fundamental for stewardship of limited vaccine supply, they can also be applied when COVID-19 vaccines are widely available, to ensure equitable and just access for all persons.

Acknowledgments

Members of the Advisory Committee on Immunization Practices COVID-19 Vaccines Work Group.

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Major Elements of the Framework for Equitable Allocation of COVID-19 Vaccine

Foundational Ethical Principles

Maximum benefit: The obligation to protect and promote the public's health and its socioeconomic well-being in the short and long term.

Equal concern: The obligation to consider and treat every person as having equal dignity, worth, and value.

Mitigation of health inequities: The obligation to explicitly address the higher burden of COVID-19 experienced by the populations affected most heavily, given their exposure and compounding health inequities.

Foundational Procedural Principles

Fairness: Decisions should incorporate input from affected groups, especially those disproportionately affected by the pandemic. Once informed by public input, decisions should be data-driven and made by impartial decision makers, such as public health officials.

Transparency: The obligation to communicate with the public openly, clearly, accurately, and straightforwardly about the vaccine allocation criteria and framework, as they are being developed and deployed.

Evidence-based: Vaccination phases, specifying who receives the vaccine when, should be based on the best available scientific evidence, regarding risk of disease, transmission, and societal impact.

Goal

Reduce severe morbidity and mortality and negative societal impact due to the transmission of SARS-CoV-2

Allocation Criteria

Risk of: 1) acquiring infection; 2) severe morbidity and mortality; 3) negative societal impact; and 4) transmitting infection to others

Four Allocation Phases

Phase 1a: High-risk health workers and first responders

Phase 1b: People with significant comorbid conditions (defined as having two or more); and older adults in congregate or overcrowded settings

Phase 2: K-12 teachers and school staff and child care workers; critical workers in high-risk settings; people with moderate comorbid conditions; people in homeless shelters or group homes and staff; incarcerated/detained people and staff; and all older adults

Phase 3: Young adults; children; workers in industries important to the functioning of society

Phase 4: All other individuals residing in the United States who are interested in receiving the vaccine for personal protection

Equity is a crosscutting consideration: In each population group, vaccine access should be prioritized for geographic areas identified through CDC's Social Vulnerability Index or another more specific index.



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Nov. 25, 2020

Dear Ankoo,

Thanks to you and to Heather Burris for asking my advice on the ethics of the initial distribution of COVID-19 vaccines. I enjoyed meeting you both and found the conversation with your scientific advisory committee stimulating and critically important to the health of the District. I am providing this formal account of my ethical analysis for your review.

The rationing of vaccines must be based on guiding ethical principles of beneficence, concern for the common good, justice, and respect for persons. As in other matters of public health ethics in a pluralistic liberal democracy, it is also important to bear in mind a principle of restraint: the least invasive, least restrictive measure needed to accomplish the public health goal is always preferable. Ethics must also always be practical, particularly in public health ethics. Some proposals might be ideally good but practically impossible to carry out. One also needs to account for both anticipated and unanticipated consequences. The sought-after benefits therefore must be measured against the psychological, social, and economic costs of any proposed policy.

With respect to COVID-19 vaccine distribution, you indicated that the District of Columbia intends to follow CDC guidelines. These guidelines place so many people in the first wave that they are not really very helpful to those who must make choices for distributing vaccine among those in the first wave. NASEM's guidelines are more helpful in this respect. The NASEM guidelines have also been in large measure endorsed by the American College of Physicians. NASEM and the ACP designate high-risk health care professionals and first responders as the initial recipients of vaccine (Phase 1a).



The ethical justification for prioritizing these persons should not be based on claims about the social worth of health care professionals. That introduces anti-egalitarian notions of measuring and comparing the social worth of persons who should, by the most basic principles of justice, all be considered of equal worth. Nor should the justification be based on a notion of reciprocity for the risks that front line health care workers undertake in doing their work. As professionals, an altruistic spirit, placing the needs of patients above their own, is already required of them.

Rather, the justification must be patient-centered. There are three patient-centered justifications for prioritizing front-line health care workers (e.g., those providing emergency medical service in the field and those working in emergency rooms and intensive care units treating large numbers of patients infected with SARS CoV-2). The first patient-centered justification for prioritizing these workers is that their continued ability to treat the sick depends upon their health. These health care workers and first responders are at high risk of exposure and possible illness. Should large numbers become sick with COVID-19, the ability of the system to care for the sick would suffer and so the negative impact of their illness upon the common good would be geometric and not merely arithmetic. Thus, considerations of general beneficence argue in favor of vaccinating front line health care workers first. The second patient-centered justification is a corollary of beneficence: non-maleficence. This is the duty not to harm patients. Health care workers treat many persons who are at high risk of contracting SARS CoV-2 infection. If those health care workers become asymptotically infected, there is a high risk of transmitting that infection to those most likely to experience significant morbidity and mortality from COVID-19. Vaccinating front line health care workers protects patients. The third patient-centered justification is that there remains deep distrust of the healthcare system and skepticism about vaccines among certain segments of the public, particularly marginalized communities that have suffered from historical abuses at the hands of medical scientists. Having a large number of health care professionals “go first” may help to assuage fears of being “experimented” upon and potentially earn the trust needed for better uptake of the vaccine in the general community, thereby redounding to the common good.

Once the health of the front line of the health care infrastructure has been secured, the NASEM guidance wisely next prioritizes those most likely to become critically ill or die should they succumb to COVID-19. While in rationing acute health care treatments (such as ventilators), priority should be on those most likely to survive, in rationing preventive measures (such as vaccines), the priority should be on those most likely to become sick and die should they not receive the intervention. With respect to COVID-19, this means the elderly (especially those living in congregate settings) and those with high-risk comorbid conditions.

It is also important to bear in mind throughout the vaccine rollout that the principles of restraint and respect for persons point to the need to safeguard the privacy and maintain the confidentiality of individuals who are eligible for vaccination except where absolutely necessary to prevent a high risk of serious harm to identifiable individuals. Even in such situations there is a duty to be as circumspect as possible.



With these general ethical considerations in mind, the District of Columbia faces an initial situation in which the anticipated allotment of COVID-19 vaccine may be insufficient to cover all front line health care workers and first responders who would be eligible under NASEM's Phase 1a. From an ethical point of view, how might one consider distributing vaccine even among this narrow group of workers?

If the guiding principle is to help patients by preventing infection in those who would care for them, then it seems that the first pass should include those at the very highest risk: those most likely to have a significant number of high risk exposures that could potentially make them sick and remove them from the workforce or transmit the infection to patients. This seems to suggest that priority should go to those at the very highest risk of becoming infected, including those at high risk of encountering repeated exposures to highly infectious inocula (such as aerosolized secretions from infected individuals), and those at high risk of repeated exposures to infected persons not known to be infected (such as EMTs and those working in the emergency department). Call these individuals Phase 1.a.i. Next in priority would be those with a high number of repeated exposures but the opportunity to identify patients infected with SARS CoV-2 and the opportunity to protect themselves against infection with proper procedures and equipment (such as ICU personnel). Call these Phase 1.a.ii. Out of respect for persons, all participation in this first phase should be voluntary.

It is also conceivable that even after limiting vaccine distribution to those individuals at very highest risk of exposure who are willing to volunteer to be in the first wave, there still might not be sufficient vaccine. In this case, a secondary consideration of risk to the individual could be invoked by prioritizing those front line health care workers who are at highest risk of personal morbidity and mortality should they become infected. This would include frontline health care workers and first responders over the age of 60 or those with comorbid medical conditions that put any person at higher risk of becoming sick and dying of COVID-19. This justification is still patient-centered in that older health care professionals and first responders often have the most wisdom and experience to contribute to the system of care through their roles in supervision, teaching, and consultation. Their loss might be thought to have a higher overall impact on the quality of patient care. Further, they would be at highest risk of being removed from the health care workforce permanently or for prolonged periods of time. This would make their infection a greater blow to the frontline health care infrastructure. Identifying such individuals in a manner that protects their confidentiality is a further ethical concern. Perhaps the best way of delivering the first tranche of vaccine to these individuals, should it be necessary, would be to identify, notify, and vaccinate them through the Employee Health offices at their institutions, where staff should have records of their age and co-morbid conditions and would also have special duties to protect the confidentiality of these individuals. A system like this seems preferable to rationing vaccine among front-line health care workers and first responders by lottery, first-come-first served, or asking individuals to self-identify as suffering from comorbid conditions. The latter procedure would endanger confidentiality and would be susceptible to gaming.



The comments above relate to the distribution of vaccine within an institution. An additional issue concerns how vaccine supplies should be distributed among institutions in the first place. Again, guided by principles of justice and concern for protecting the most people possible, I would suggest distribution proportional to the numbers of cases of COVID-19 treated to date—that is—the hospital seeing the most cases gets the most vaccine. Thus, the communities hardest hit by COVID-19 will be given the most protection.

Above all, it should be noted that this phasing is not a plan for who should get vaccine and who should not, but how to sequentially deliver a vaccine that eventually *everyone* should receive. The temporal sequencing is guided by concern for the common good—how to roll it out in ways that are designed to help the community as a whole.

Finally, I would argue that there is an ethical obligation to be grateful that we have the problem of how to allocate a vaccine for COVID-19. Never before in human history has an infectious disease arisen *de novo*, its microbial cause been elucidated, its genome sequenced, and vaccines to prevent it made available within 12 months. We owe a debt of thanks, this Thanksgiving, to the health care professionals, scientists, and public health workers who have made this possible.

I hope that these thoughts are useful to you and your team. Thanks to you and Heather for your dedication to this work and for thinking about the importance of ethics in this vaccine distribution effort. The citizens of the District are lucky to have you serving them!

I look forward to further conversation and stand ready to assist in other ways should my expertise in ethics seem useful.

Sincerely,

A handwritten signature in blue ink that reads "Daniel P. Sulmasy". The signature is written in a cursive, flowing style.

Daniel Sulmasy, MD, PhD